UNDERREPORTING FEDERAL INVOLVEMENT IN NEW TECHNOLOGIES DEVELOPED AT SCRIPPS RESEARCH INSTITUTE

Y 4. SM 1: 103-93

Underreporting Federal Involvenent...

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY

OF THE

COMMITTEE ON SMALL BUSINESS HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

WASHINGTON, DC, JULY 11, 1994

Printed for the use of the Committee on Small Business

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UNDERREPORTING FEDERAL INVOLVEMENT IN NEW TECHNOLOGIES DEVELOPED AT SCRIPPS RESEARCH INSTITUTE

MONDAY, JULY 11, 1994

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES, AND TECHNOLOGY,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:40 a.m., in room 2359–A, Rayburn House Office Building, Hon. Ron Wyden (chairman of the subcommittee) presiding.

Chairman WYDEN. The subcommittee will come to order.

Today the Subcommittee on Regulation, Business Opportunities, and Technology continues its inquiry into the protection of vital public rights in biomedical technologies developed through Federal funds. Specifically, the subcommittee will examine flaws in procedures at the National Institutes of Health for monitoring and protecting a variety of public rights to federally funded scientific innovations, which lead to a wide variety of new drugs and medical devices.

This is a matter of great importance to our taxpayers. The Government is now paying almost $8 billion through the National Institutes of Health annually and to a lesser degree, through the National Science Foundation, to fund research on medical breakthroughs and this money goes to scores of colleges, universities and medical institutions.

As a result of this enormous Federal investment, the Federal Government has certain rights and interests including an assurance of reasonable pricing and availability of products commercialized as a result of this research.

In addition, the taxpayers have an interest in assuring that these technologies are developed and manufactured in a way that creates family wage jobs in our country. Specifically, the Government can use its leverage to force co-licensing of technologies and competing drugs or devices.

In the case of flagrant disregard of the public interest, the Government can even take ownership of a patent. Today, the subcommittee is examining an audit done at our request by the Inspector General of the Department of Health and Human Services. The audit states fundamental problems exist within the National Institutes of Health's ability to monitor the scores of institutions who benefit from the billions of dollars per year in Federal research lar-

gess. Further, the auditors found that the National Institutes of Health lacks information to ensure compliance with the law and regulations.

Unfortunately, the current system often fails to record taxpayers' interest in the technologies and safeguard important public rights. The Inspector General has used the Scripps Research Institute as a case study. Initially, some 18 months ago, the National Institutes of Health records indicated to the Inspector General that only 5 of 125 patents issued to Scripps over the last decade had some Federal grant involvement.

When the Inspector General contacted Scripps, the Institute initially admitted to 51 patents with Federal Government support. More than a year later, and after prodding from the Inspector General, Scripps has admitted to 94 patents that had Federal funding.

The central problem, says the Inspector General, is that institutions are functioning according to a voluntary honor code. Whether grantees choose to reveal the Government's involvement or not appears to be entirely discretionary. The National Institutes of Health enforcement system seems toothless. In effect, the National Institutes of Health seems dependent on a policy of don't ask, don't tell, and don't pursue.

At a minimum, an $8 billion research program is too large to operate with the Federal Government allowing private interests to say trust us. The Chair believes that it is highly unlikely that these institutions will plug the meter if there is no parking enforcement by the National Institutes of Health.

Now, this is not just a theoretical issue. One successful example of protecting taxpayers' interest is the Government's handling of AZT, the AIDS drug. Burroughs Wellcome had priced this Federal-financed drug sky high, well out of the reach of many patients. Using the provisions enacted by the Congress for the purposes of commercializing Government-supported technologies, the Government said it would sue Burroughs to force co-licensing the drug. This would have created competing AZT products and potentially lower prices for the consumer.

Because the Government used its leverage to protect the public, Burroughs Wellcome sliced its price in half, not once, but twice. Again, the key was that taxpayer involvement in funding the underlying research was carefully described in the AZT patent.

The chair believes that Scripps is a microcosm of a much larger problem inflicting the entire National Institution of Health extramural research community. Outside of the scope of the Scripps audit, the Inspector General has disclosed to us that a rudimentary analysis of patent activity at several other large federally financed research institutions around the country indicates similar disproportionately low levels of Federal support ascribed to technologies underlying patents issued to these institutions.

To quote from the Inspector General in a letter to Assistant Secretary of Health Phil Lee, "We believe that annual audit work is warranted to determine the full extent of this problem."

Now, the response of the National Institutes of Health to the troubling report issued by the Inspector General seems underwhelming. For example, the Inspector General has recommended that the National Institutes of Health should develop a

procedure to allow it to obtain information directly from the U.S. Patent Office with regard to patents issued to all of the grantees of the National Institutes of Health.

With this information, the National Institutes of Health, Division of Extramural Invention Reports should determine whether patented inventions were supported by Federal funds. Instead of better protecting the public interest, unfortunately the National Institutes of Health wants to continue business as usual, sticking with the system that is overly reliant on grantee's voluntarily doing the right thing.

The National Institutes of Health seems to argue that watchdoging the taxpayers' rights to these technologies will be, quote, "an enormous burden." The subcommittee is going to be very interested in knowing what burden is posed by a computerized system that would file the reports establishing the taxpayers' interest electronically and with the assistance of the patent office.

The National Institutes of Health should perform its job on tracking and auditing or in the alternative hire an outside contractor for this duty. This is an idea that our colleague, Congressman Combest, is examining. I think it might be an entirely appropriate fix if the National Institutes of Health can't perform or refuses to perform the important mission of watchdoging Federal involvement in scientific research.

No doubt, this would be a good opportunity for small businesses already involved in auditing of this type on a consultative basis.

Another approach would be to hand over the enforcement task to the Department of Commerce, which does have some oversight responsibilities in this area. If the National Institutes of Health makes the case that it is a commerce job, then I will request that within a time certain, the National Institutes of Health and the Commerce Department draft and sign a memorandum of agreement that describes exactly what each one could do separately and together to solve the problem.

The public deserves better than the status quo. The taxpayer deserves a better system than the one proposed by the National Institutes of Health and the Public Health Service. We thank all of our witnesses for their cooperation. We welcome them today.

Before we go to our witnesses, let me recognize our colleagues. The gentleman from Texas, Mr. Combest, is always one who I enjoy working with. I want to thank him for his cooperation and his excellent suggestions and recognize him for his opening statement.

Mr. COMBEST. Thank you, Mr. Chairman. I thank you for holding this hearing and for your opening remarks.

Today's hearing is another in a series that has examined the Scripps Research Institute's compliance with the provisions of the Bayh-Dole Act.

As I understand, also at question today is compliance with the National Institutes of Health with its responsibilities under Bayh-Dole. This case we already know the juicy parts of the story. Scripps and NIH have been found to be remiss under its responsibilities of Bayh-Dole. Each has acknowledged their failing. Although Scripps is held up for examination today, we shouldn't be surprised to learn that other institutions also may not have done a good job with their bookkeeping.

I would like to gain a better sense of this disclosure failure and perhaps when NIH has straightened out their records we can find out. I have two principal questions remaining. One, what will NIH and Scripps do to come into compliance with the Bayh-Dole Act; and, two, how can we be sure that our federally sponsored researchers will act in the public's interest? Hopefully, our witnesses are prepared to speak to those concerns.

On many occasions, this subcommittee has heard excellent testimony celebrating the success of the Bayh-Dole Act. Those successes are something agreed to by the Federal funding agencies, academic research institutions and industry. Where we have observed shortcomings in Bayh-Dole, I will look forward to working with Chairman Wyden and the experts to provide a clearer and more effective law. I would seek a sensible balance between full accountability to the taxpayer and unfettered business opportunities. We have a big responsibility.

The history of cooperation between academic research institutions, Federal funding agencies and corporations have been and continue to be quite successful. The results are seen in good paying jobs in the private sector and enhanced competitiveness in an international economy, and most importantly, new treatments and cures for the American people. Thank you, Mr. Chairman.

Chairman WYDEN. I thank my colleague, and I also want to recognize our good friend from Missouri, who has long been an advocate of assuring that consumers get reasonably priced pharmaceuticals and that taxpayers are protected.

Mr. SKELTON. Thank you very much. Let me briefly compliment you on this hearing. This is a well-thought out, well-planned hearing on a very important subject. The American taxpayers are entitled to some answers and you are about to seek them.

The bottom line is making sure that federally supported inventions meet the needs and protect the public against the use or misuse of these inventions. I also know that because of the nature of this subcommittee, it is meant to encourage the participation of small business firms in the support of research, and when I chaired a comparable subcommittee last year, we were very involved with that very issue of encouraging through Federal dollars various inventions and follow-through, making sure that they at least have the opportunity to be used for the public good.

We are talking about a lot of money here; a lot of money here. I know in another forum such as if this had been the Pentagon, this would be front page already. I think this should get the same type of scrutiny as if it were something of that nature.

Chairman WYDEN. Let me thank my colleague for his comment, particularly your point about the very large sums involved. We are talking about $8 billion. I think, as the gentleman knows, this will increasingly be the kind of research of the future. With declining Federal support, we are seeing more of these kinds of cooperative arrangements between the public and the private sector.

I think both of us share Mr. Combest's view that there are many benefits to this. Certainly, the taxpayers' interests have to be foremost, and there seem to be some flaws. The gentlemen have been correct in highlighting the large amount of money involved and why this subcommittee is pursuing this. I want to thank him.

Mr. SKELTON. Let me add, if I may. In this tight budget environment in which all of us in Congress are working, it is important that these moneys, the Federal involvement in these new technologies, be spent properly, correctly and that oversight is absolutely necessary. A hearing such as this will help not only set the record straight, but hopefully will set, as you are hopeful, a memorandum of understanding so that we can be assured and that the public can be assured of proper spending of this money. It is a lot of money we are speaking about, $8 billion. That is a lot of money.

Chairman WYDEN. I thank my colleagues for their statements. Let us go right to our witnesses. Michael R. Hill, the Assistant Inspector General of the Department of Health and Human Services. Mr. Hill, welcome.

Mr. Hill, do you desire to be accompanied by associates today?

Mr. HILL. Yes, Dave Pryal is going to help with the visual aids. He was the Audit Manager, on the Scripps Audit. The Audit Director was Mr. Frank Zuraf on this particular assignment.

Chairman WYDEN. It is the practice of this subcommittee to swear all the witnesses that come before us. Do you have any objection to being sworn?

Mr. HILL. No, sir.

[Witnesses sworn.]

Chairman WYDEN. Gentlemen, we thank you. We will make your prepared remarks a part of the hearing record in their entirety. If you will highlight your principal concerns in your prepared remarks; that will leave plenty of time for questioning. Please proceed as you wish, Mr. Hill.

TESTIMONY OF MICHAEL R. HILL, ASSISTANT INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC; ACCOMPANIED BY DAVE PRYAL, AUDIT MANAGER AND FRANK ZURAF, AUDIT DIRECTOR

Mr. HILL. Thank you, Mr. Chairman. Good morning, Mr. Chairman, and members of the subcommittee.

Chairman WYDEN. I think if you could push that microphone closer to you, that would be great.

Mr. HILL. Thank you, sir.

As I said, I am Michael Hill, Assistant Inspector General for Audit at the Public Health Service. Mr. Frank Zuraf, is the director of Audit and Mr. Dave Pryal is the audit manager on this assignment.

I am pleased to be here to share with you the observations, the findings, and the recommendations from two Office of Inspector General reports.

Mr. Chairman, the first report you requested dealt with underreporting the Federal involvement in new technologies developed at Scripps Research Institute. We issued that report in May 1994.

The second assignment was an inspection conducted by our Office of Evaluation and Inspections, entitled NIH Oversight of Extramural Research and Inventions, which was basically an inspection of NIH's ability to monitor grantees' compliance with laws and regulations dealing with invention reporting.

As the Nation's premier biomedical research institution, NIH accomplishes its mission, in part, through funding research at grantee institutions such as universities, medical schools, hospitals, and research organizations. Chart two gives a perspective on the amount of funds involved.

In 1992, fiscal year, we are talking about $6.2 billion, and in fiscal year 1993, we are talking about research grants of about 30,000 involving $7.3 billion. That is just at NIH. That is about 70 percent of NIH's budget, Mr. Chairman.

Critical issues dealing with grantee invention reporting and ownership of inventions resulting from federally funded research are addressed in the Patent and Trademark Amendments Act of 1980, which is commonly known as the Bayh-Dole Act. The act, which has several objectives, allows grantees to acquire title to inventions and file for a patent application for technologies developed with Federal research funds. Grantees then can earn royalty income by providing industry with exclusive or nonexclusive licenses to patented inventions.

Charts 3 and 4 identify the objectives of the Bayh-Dole Act: To ensure that United States obtains sufficient rights in federally supported inventions to meet its needs and to protect the public against nonuse or unreasonable use of inventions; promote utilization of federally supported inventions; encourage maximum participation of small business firms in federally supported research and development efforts. Four, promote collaboration between commercial concerns and nonprofit organizations including universities; ensure grantee inventions are used in a manner to promote free competition and enterprise; to promote commercialization and public availability of inventions by U.S. industry and labor, and minimize administrative costs.

With such a large investment of public funds in research, it is important to ensure that the interests of the American taxpayers are protected. Yet, in our work, we have indications of underreporting at Scripps, and that fundamental problems exist with NIH oversight of grantee compliance with Federal regulations implementing that Bayh-Dole Act.

Before discussing our inspection, Mr. Chairman, I would like to discuss the audit report that you requested. Specifically, you requested that we look at 130 patents issued to Scripps and provide the subcommittee with an assessment of whether the Federal involvement in underlying technologies had been properly reported in Scripps patent applications. I think a little background on the NIH-Scripps relationship is important, Mr. Chairman.

In 1993, about $75 million was provided from NIH to Scripps. Over a 10-year period, 1984 to 1993, over a half a billion dollars went from NIH to Scripps. Information we obtained in April 1993 from NIH showed that only 51 of the 125 patents awarded to Scripps were developed with the assistance of Federal grant funds. After we raised questions, 43 more were identified by Scripps in June.

In short, Scripps' patents didn't always disclose inventions were supported with Government funds; 43 times out of 94. It is not a very good record.

To give you an idea of the grantee obligations, Mr. Chairman, the grantees are obligated to disclose the invention within 60 days, elect whether to retain title within 2 years of disclosure, file patent applications within 1 year after retaining title, include Government rights clauses in the patent application, and provide the Government a nonexclusive license.

Because of the underreporting we found at Scripps, we performed a very cursory review of reporting practices at other institutions. We examined data on 25 universities with the most patents, involving over 4,500. We found that only 1,818 or 37 percent contained the Government rights clause, and if you recall, Mr. Chairman, that is a similar percentage as the 51 that were identified by Scripps initially in April 1993. That percentage was about 41 percent, and then it increased to over 75 percent once we raised questions on that assignment.

The percentage—37 percent—is a concern to us. We provided NIH with a copy of our list and requested that the NIH ask the 25 universities to review the patents and determine if they may also have underreported the Federal involvement in the development of the patented invention. The NIH concurred with us and they are looking into that now, Mr. Chairman. I am sure they will tell you more about it during the NIH testimony.

The audit conclusion was that because NIH was unaware of patented inventions Scripps developed with NIH funds, NIH cannot assure that the objectives of the Bayh-Dole Act are being met. Just to give you a perspective, Mr. Chairman, NIH really did not have very good records when we started this assignment. I was looking at a letter dated April 26, 1993, from the NIH Director of Extramural Invention Reports Office to Scripps. What this letter says is this, just a couple of sentences, Mr. Chairman: "We were surprised to learn from published newspaper accounts that the Scripps Institute holds title to about 130 patents." My point is that NIH is surprised by the statistics.

Chairman WYDEN. NIH learned about it from the newspapers?

Mr. HILL. That is what this letter says, Mr. Chairman.

It further states: "After an exhaustive search through 150 Scripps case files in our office records, we found only 13 patents identified on the enclosed list. Unfortunately, only five of these acknowledged the Government support." But I think this is acknowledgment by NIH that the records were in disarray when we started this assignment.

Earlier this year, in May of 1994, we issued an inspection report and I will try to give a brief overview of the inspection. We found that NIH does not fully utilize its invention database to monitor grantees.

The primary role in ensuring that the grantees comply with Federal regulations for inventions. The primary reporting responsibility, certainly, belongs to the grantees, but at the same time, NIH must oversee the reporting to ensure grantee compliance. The weak NIH oversight of the past simply did not work.

NIH lacks a systematic process for ensuring that grantees submit all required invention information. The NIH does not review invention disclosures and elections of title for timeliness and doesn't know if grantees are in compliance. NIH does not examine

annual utilization reports to monitor grantee commercialization efforts. The NIH has no system to ensure timely filing of patent applications.

As I think about this, Mr. Chairman, NIH should be thinking more proactively. The NIH managers should be thinking what outputs do we want from our investment, (i.e. the $7 or $8 billion annual investment). What outcomes do we want? How do we plan to achieve the objectives of the Bayh-Dole Act? List those outcomes and outputs that they want to achieve. Set up goals. Set up objectives to achieve the goals. Identify targeted amount and measure how they are progressing. That is what we are asking, Mr. Chairman.

The OIG recommendations are: Examine the remaining patents Scripps claims were not developed with Federal funds and determine if Scripps' assessment is correct. One thing we learned concerning the recommendation, Mr. Chairman, is that NIH was in the process of reconciling 35 SRI patents to determine if the Government supported their development. We asked NIH to do that.

Preliminary information indicated that 11 were developed with Federal support and 24 were developed without Federal funds. Of the 11, 1 was a fellowship grant which is exempt, 8 were funded by NIH grants issued before the passage of the act, when it was not a requirement that a Government support clause be added to a patent application, and the remaining two are still under review. We were informed of this by the Assistant Secretary of Health in May of 1994, Mr. Chairman.

The other OIG recommendations are: Determine the extent of noncompliance by other grantees with the Code of Federal Regulations reporting requirements and NIH guidelines; NIH should develop procedures to obtain U.S. PTO information on patents issued to grantees and determine if such inventions were supported by NIH funds.

NIH should also improve monitoring of grantee compliance with the Bayh-Dole Act requirements and NIH should collect more detailed licensing and utilization information and track grantees for timely compliance.

Mr. Chairman, we appreciate your interest and support in examining these important program issues. As the Government's investment in Federal research dollars continues to rise, it is of the utmost importance that the American citizens are ensured of a fair return on their tax dollars where a return is warranted.

When the Government is not aware of the grantee's invention, it is unable to exercise its rights and to protect the taxpayer's interests. According to NIH and Department of Commerce officials, when a grantee develops a new technology supported with NIH funds, the Government has the right to obtain the technology without paying a royalty, which is normally included in the purchase price of the product. If the Government is not aware of situations where it might obtain nonexclusive licenses, it may be missing opportunities for savings on purchases of medical supplies or devices.

Although our work has identified a weakness in NIH's oversight in this area, it is important to remember that the primary reporting responsibility rests with the grantees. I hope and trust, based on your work, Mr. Chairman, and the work of the HHS IG, that

the grantees will review their reporting and improve where needed. I also hope grantees will take a fresh look at the Bayh-Dole Act objectives and make improvements where needed.

We are encouraged by recent NIH efforts to improve its stewardship of extramural research inventions. I am sure that NIH plans to elaborate on these efforts in testimony it will provide on the next panel. This concludes my remarks, Mr. Chairman. Thank you for including us in this important dialogue. At this time we would be happy to answer any of your questions.

[Mr. Hill's statement may be found in the appendix.]

Chairman WYDEN. Thank you very much, Mr. Hill. Let me first commend the Inspector General. You, Ms. Brown and your entire office have done a terrific job in terms of dealing with this issue. I think it is quite clear that patents would not qualify as one of the great, scintillating, sexy, glamorous kinds of issues on American public policy. But what you have very clearly laid out, is that the taxpayers have enormous interests here. This is a very significant sum of money. It is growing.

The taxpayers' interests haven't been adequately protected or addressed, and we are going to stay with it. Your good work has really lit a spark around this issue, and we commend you for it. I am going to have some questions in a moment, but I have a couple of good questioners here who are going to start. We will begin with the gentleman from Texas.

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. Hill, you may not have the answer to this question, but using your own figures here in 1993 of $7.3 billion, Scripps received, I believe, you said later on $74 million, ballpark figure of 1 percent of the amount awarded in 1993 went to Scripps. Do you have any idea of the research grants, 29,529, how many of those went to Scripps?

Mr. HILL. Yes, sir, I think I do.

Mr. COMBEST. Do you recall just a ballpark figure?

Mr. HILL. It seems to me it was less than 2,000.

Mr. COMBEST. OK. So, we are talking about—let's see, it was 2,000. Then if I am figuring this correctly, we would be talking about less than 1 percent of the grants and about 1 percent of the money would be awarded to Scripps; would that be correct?

Mr. HILL. Yes, sir, it would be.

Mr. COMBEST. So we would assume from this that Scripps is not the only culprit. The problem out there we are sort of honing in on Scripps, but with only less than 1 percent of the grants and about 1 percent of the dollars, the chances are there is a problem existing elsewhere other than Scripps. Would that be correct?

Mr. HILL. I think that would be correct. Congressman, the number of grants over a 10-year period was 2,138 for Scripps. That involved the $521 million, 1984 to 1993. We do not have the figure for 1993, but I wanted to give that perspective.

Mr. COMBEST. That is 2,000 over the entire time?

Mr. HILL. That is correct. When I said under 2,000, it would certainly be under 300 for 1993. I am sure they will have the answer for you, sir.

Mr. COMBEST. I was trying to get an idea about the size in terms of the total amount awarded both in terms of numbers and in

terms of grants, and just to try to see how large of a bite of the pie that Scripps might be taking. So, it would seem to me that it is pretty obvious that it is out there in addition to that.

I guess one of the determining—lack of information being adequately provided, it would be hard for anyone to question any company's activity. For example, if you had a small business concern and would like to be a participant in the grants and the monies that are awarded for research, without all of the information being provided, they really would have a lack of database on which they could make an argument that, in fact, they had been left out. They would know if they had been left out, but in terms of actually knowing what the amounts were relative to bigger competitors, without having an adequate database or an accurate database by which they could draw a complaint, then they would be pretty much out in the cold.

Mr. PRYAL. Yes, that is correct. The NIH doesn't maintain a listing of who grantees' licenses. So, NIH can't tell you right off the bat how many of its grantees licenses with small business, how many licenses are with big businesses, et cetera.

Mr. COMBEST. In the awards for Scripps—again, it seems that we are singling them out and I don't want to do that, but that is where the data is and that is why I asked the first question that I asked, but, for example, in the information on Scripps, I believe the number changed from, what was it, 51 to 94 as the——

Mr. HILL. That is right.

Mr. COMBEST As this began to be looked into there were 51 and then there were 43 more. Is there any category that one could put in the 43 that were not initially listed in April of 1993 that have been added in June of 1993. I guess what I want to try to find out, is there something about those that might be a little suspect of why they weren't out there or do you think it was purely oversight or whatever?

Mr. HILL. We think it was just oversight. There did not seem to be a pattern of why some were excluded and others included.

Mr. COMBEST. Do you know if NIH has fully agreed now with the IG's recommendations? Are they convinced the IG—that NIH's approach is sufficient?

Mr. HILL. They have come quite a ways from the response to our final audit report that they received in May. I give this subcommittee credit for that. You will hear from the NIH officials shortly. We want to follow up to see if what NIH plans to do is effective. We think they can be in a lot better position of knowledge than they currently are.

Mr. COMBEST. Do you look into or when you are looking into this, do you take into consideration, or was one of the reasons for some of the lack of compliance in the past, staffing problems or lack of resources which are pretty stretched anyway in all the Government and all agencies?

Mr. HILL. We didn't look specifically at that, but we did observe that only two people were assigned to this task and that is clearly not enough.

Mr. COMBEST. It is my understanding that under Bayh-Dole also there is no penalty established for noncompliance with this particular section. Is that correct?

Mr. HILL. NIH has not used any penalties in enforcing the Bayh-Dole Act.

Mr. COMBEST. They do have the authority to impose the penalties?

Mr. HILL. There are certain things that they could do that they have not done. Nondisclosure, for example, there is——

Mr. COMBEST. The law doesn't require penalties, does it?

Mr. HILL. The law does not require penalties; however, NIH may claim title to the invention after it finds timely disclosure was not made.

Mr. COMBEST. Is that due mainly that this was not a fact of priority for NIH, in your opinion?

Mr. HILL. I just think that two NIH people were not enough. The NIH was dealing from a position of weakness, that is, insufficient. The April 1993 NIH letter that I referred to in my oral testimony talks about NIH, conducting an exhaustive search through 150 Scripps case files, only to find 13 patents. It just shows the NIH system was in disarray. So, the information was in such disarray that NIH was dealing from a position of weakness.

Mr. COMBEST. Thank you, Mr. Chairman.

Chairman WYDEN. Gentlemen, perhaps I will ask it. Mr. Hill, I understand that they may have only one person there now. They used to have two and one retired; is that correct?

Mr. HILL. Yes, sir, that is correct.

Chairman WYDEN. So we have one person watchdoging this $8 billion program. Unbelievable. The gentleman from Missouri.

Mr. SKELTON. So we understand what we are talking about, through the NIH, Federal funds are given to various companies, inventors, small businesses, not-for-profit organizations and the like, to pursue medical-oriented inventions; is that right?

Mr. HILL. Yes, sir, the funds are provided for research.

Mr. SKELTON. Under the law known as the Bayh-Dole Act, a 1980 statute, these people, upon getting a patent with partial funds from the NIH, which is taxpayers' dollars, must so state and tell the NIH so the NIH can promptly claim the Government rights that accrue to it under the Bayh-Dole Act; is that right?

Mr. HILL. Yes, sir.

Mr. SKELTON. Now, when a corporation does not so disclose that this patent was paid for either in full or in part with the taxpayers' dollars coming from NIH, that is a violation of the Bayh-Dole law; is that not correct?

Mr. HILL. Yes, sir, Federal support must be reported in the patent.

Mr. SKELTON. There is a penalty clause in the Bayh-Dole Act, the most stringent penalty being that the Federal Government, the NIH, can take back this patent; is that right?

Mr. HILL. That is correct, sir.

Mr. SKELTON. That has never been done?

Mr. HILL. That is correct, sir, the Government can license the patent to others.

Mr. SKELTON. There has never been any enforcement of the Bayh-Dole Act under this clause; is that right?

Mr. HILL. It has been absolutely minimal, that is for sure.

Mr. SKELTON. Well, can you think of one instance where there was any enforcement of this Government rights clause under the Bayh-Dole Act? Name one. Can you name one?

Mr. HILL. No, I can't name one with the Government granted rights to another. Based on the interest of this subcommittee, NIH did go out to Scripps and ask them to do a better job reporting.

Mr. SKELTON. No, no, no, that is not answering my question. Has action been taken to remove the patent rights from anyone under the Bayh-Dole Act?

Mr. HILL. No, sir.

Mr. SKELTON. The law says that there must be a disclosure to the NIH within 60 days of an organization or company obtaining a patent; is that right?

Mr. HILL. Yes, sir, NIH must be informed within 60 days of the discovery of the invention.

Mr. SKELTON. That is really what we are talking about. We are really talking about the American public, through the tax dollars that they pay, which are given to NIH, receiving certain rights under this Government clause which says that if a company with partial or full funding from NIH, which is tax dollars, doesn't develop this or produce this whatever it is, a process or device or a drug, which, of course, is in the public interest, if they don't do it, if they just sit on it, then the Government, through NIH, says this is for the public interest, and we will see that it is produced for the American public; is that right.

Mr. HILL. Yes, sir.

Mr. SKELTON. That is the purpose of this whole thing; is that not correct?

Mr. HILL. That is one of the purposes; that is for sure.

Mr. SKELTON. As I understand it, looking at the Scripps situation, there were some 43 unreported patents that were developed with Federal funds through the NIH; is that correct?

Mr. HILL. Yes, sir.

Mr. SKELTON. Do you agree that if this were NASA or the Pentagon, this would be a highly publicized story?

Mr. HILL. I think so, sir.

Mr. SKELTON. Now, I am going to ask two things. I am going to ask the Chairman, if he agrees, that the Patent Office should ask each new medical-oriented patent applicant if Federal funds are involved, and that answer be submitted to them under oath. Would that be a good idea?

Mr. HILL. I like that idea, sir.

Mr. SKELTON. I also am going to ask 1 year from now through this Chairman what governmental rights have been reclaimed or what action has been taken under the Bayh-Dole Act or what patents have been taken back because of noncompliance with the Bayh-Dole Act. I would like to see what happens within the next 365 days, and if that is suitable with the Chairman, I would hope that this subcommittee could submit that question to you. Thank you.

Chairman WYDEN. I think the gentleman's requests are very reasonable. Let us say working in consultation with our Minority, Mr. Combest in particular, we will work to have those questions posed. The gentleman, I think, hit right on it. The gentleman is an expert

in Pentagon matters and military matters. He is correct in saying that if this kind of thing occurred at the Pentagon, people would be screaming their lungs out. The gentleman is very correct to——

Mr. SKELTON. I might add, Mr. Chairman that, the Pentagon dollars are the same as dollars going to NIH. They are all funded from the American taxpayer. This is all for the American citizen. In the case of NASA or the Pentagon, it is for national security or something related thereto, but in this case, it is American health and they should be treated the same.

Chairman WYDEN. The gentleman is perhaps being too logical on these matters, but they do, in fact, come from the 1040 forms filled out by the taxpayers of this country. Clearly, the taxpayers' interests are not being addressed when you have an $8 billion program that Mr. Hill describes. When he came in contact with it, the records were in disarray, and two people were involved. Now, it appears that there is only one person who is specifically assigned to it. I am very curious about the voluntary nature of a program that the National Institutes of Health seems to think is adequate, Mr. Hill.

Today's program is voluntary, and, as Mr. Skelton has pointed out, it failed. It failed in the instance of Scripps where you had a situation where they initially found five patents on the basis of the records, then they found 51, then 94. Who knows what it is going to be next?

But I am curious. Do you think that a voluntary system is good enough when you are talking about $8 billion worth of failures discovered by your audit?

Mr. HILL. No, sir. The self-monitoring program that was used with the grantees did not work.

Chairman WYDEN. What exactly is so burdensome about a computerized system that would file the reports establishing the taxpayers' interest electronically and with the assistance of the Patent Office? I have seen all kinds of comments by Dr. Lee and others at the Public Health Service about what a great burden is being imposed on the agency. What exactly is so burdensome about having a decent computerized system?

Mr. HILL. It is really not a burden at all, Mr. Chairman. As a matter of fact, NIH has developed an easy to use reflex database for storing information on inventions. We believe that they could modify what they already have; utilize information from the Department of Commerce and also from a commercial database called Dialogue, and based on those two distinct databases, do some sort of risk analysis. I am not asking them to look at every one, but I do think they should look at the ones that are most vulnerable—i.e. a risk-based approach.

When you think about some of these others like the University of California system which received more than $500 million, I believe, in fiscal year 1993, reporting about 41 percent of their patents contained the Government rights clause; or the University of Minnesota, 36 percent——

Chairman WYDEN. Let us just go a little slower here. You have found that the University of California, based on your audit work, is in essentially the same ballpark as Scripps and others?

Mr. HILL. It was only a cursory review or a preliminary finding, but the percentages are very similar. So what I am saying is that we did this cursory analysis in hours. We looked at the top 25 schools. It was not a lot of work. It can be done easily and it should be done. Self-monitoring did not work, so a new approach should be tried.

Chairman WYDEN. You mentioned the University of Minnesota. What did your preliminary analysis find at the University of Minnesota?

Mr. HILL. We found that PHS funding in fiscal year 1993 was over $100 million. There were 285 patents. Of those, 104 we believe included the Government rights clause. The percentage would be about 36 percent.

Chairman WYDEN. Were there other major research institutions that you looked at in your rudimentary analysis that would be helpful to us?

Mr. HILL. There are a number of others that we took a look at. Stanford, we believe that the number of patents involved are 483 and the Government rights clause included 187, or about 39 percent. But there were quite a few others that we looked at. The weighted average of the percentage was something very similar to what we found at Scripps initially—i.e. 51 patents out of 125.

Chairman WYDEN. With respect to the Scripps situation specifically, does it mean that the Federal Government could call in the 70 or 80 inventions that Scripps failed to disclose over the decade, which was the focus of our audit? Could the Federal Government call those in according to the law?

Mr. PRYAL. I don't think so. I think the time has elapsed. I think NIH had about 60 days to act after it found out that Scripps did not disclose an invention. It has been more than 60 days since NIH found out about the invention and nothing happened in those 60 days.

Chairman WYDEN. So basically, the only thing that spares Scripps in this situation is that the Federal Government let the statute of limitations run out?

Mr. PRYAL. Yes, I believe so.

Chairman WYDEN. Now, over the period of the audit had an exclusive technology licensing agreement with Scripps. According to Scripps in sworn testimony before this subcommittee, Johnson & Johnson acquired licenses to many of the technologies that were not reported. But only one or two of the dozens of technologies were commercialized. So, there seems to be a fair amount of evidence that Johnson & Johnson sat on innovations that were funded by the taxpayers.

In your view could NIH make a case to claim those patents for the public under Bayh-Dole? I guess this is another statute of limitations question. Let's frame it this way: If the statute of limitations had not passed, in your view, Mr. Hill, under Bayh-Dole, could the Federal Government make a case to claim those patents for the public?

Mr. HILL. I guess the way I would answer that, Mr. Chairman, is that NIH is not looking at use, which is very unfortunate. They are not looking at licensing. So, they are not in a position of strength, of knowledge.

Chairman WYDEN. What you are saying is that the case is there to be made, but NIH is essentially not prepared to make it?

Mr. HILL. The case may be there to be made. At Scripps I think you will find when you talk to them later that the number that are actually being used is quite low also. But again, NIH needs to do a better job in monitoring the objectives of the Bayh-Dole Act.

Chairman WYDEN. Why do you think NIH is dawdling so in setting up a really aggressive program to protect the taxpayers' interests? We are talking about something which could be addressed with a decent computer system. You also said it is not as undue a burden as the Public Health Service seems to indicate. I am curious about your opinion as to why the National Institutes of Health is dragging its feet when a program to protect the public is so obviously necessary?

Mr. HILL. I am not sure of their motivation, but intuitively I think, Mr. Chairman, that they assumed that the grantees would do a better job, and they should do a better job. We are giving them over $7 billion in fiscal year 1993, and we are only asking that the objectives of this act be achieved. They should do a better job. I think NIH trusted that they would, and there was a failure there. So, both look bad, in my view.

Mr. PRYAL. I would like to add that most of the patent activity is only at about 25 schools. You know, we are not talking about 1,000 schools out there. So, if you would just concentrate on these 25 schools, NIH should be able to do a very good job.

Chairman WYDEN. Well, let me see if my colleague has any additional questions.

I think you have performed a great service for the country. This is something that has gone undetected for too long. We are going to shake up this system and try to make sure that that $8 billion gets used as Congress intended. That is to get cures to dreaded diseases out to the American people, make sure that those products are reasonably priced, and make sure that the American people have access to good family wage jobs wherever possible in the development of these technologies. You have made this job easier by doing such superb investigative work.

We will be working very closely with you. Please offer our commendation to Ms. Brown, because I think this is first rate work and a service to the country. Unless you have anything to add further, I will excuse you at this time.

Mr. HILL. Thank you, Mr. Chairman.

Chairman WYDEN. We thank you all.

Our next panel, Dr. Wendy Baldwin, Ph.D., Deputy Director for Extramural Research, National Institutes of Health, accompanied by Geoffrey Grant, the Acting Director of the Office of Policy for Extramural Research Administration, also Dr. William H. Beers, senior vice president of the Scripps Research Institute, accompanied by Douglas A. Bingham, general counsel.

Dr. BALDWIN. Mr. Chairman and Members, I am Dr. Wendy Baldwin. Since January——

Chairman WYDEN. Doctor, before you proceed, it is the practice of this subcommittee to swear all of the witnesses who come before us. I assume Mr. Grant will accompany you and testify and respond to questions as well. Very good.

Dr. Beers, you are accompanied by Mr. Bingham. Do you anticipate Mr. Bingham participating in some of the responses?

Dr. BEERS. Yes, I do.

Chairman WYDEN. We welcome all four of you this morning. It is our practice to swear all witnesses. Do any of you have any objection to being sworn as a witness? Please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. We thank all of you for your cooperation with our subcommittee. We will make your prepared remarks a part of the hearing record in their entirety. Perhaps in the interests of time, if you could summarize some of your principal concerns, that would be helpful.

Dr. Baldwin, if we could get that microphone right in front of you, that would be great, because we do have infernal microphones in here. Welcome. Please proceed.

TESTIMONY OF WENDY BALDWIN, PH.D., DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND ACCOMPANIED BY GEOFFREY GRANT, ACTING DIRECTOR, OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION

Dr. BALDWIN. Thank you very much. I am Dr. Wendy Baldwin. Since January 1994 I have been NIH Deputy Director for Extramural Research. I am pleased to appear before you today and answer questions about some aspects of the Bayh-Dole Act.

The Bayh-Dole Act as amended permits institutions and small businesses who receive Federal funds to retain title to federally funded inventions and encourages them to commercialize inventions. The overarching goal is to ensure that such inventions are made available to the American public. Under Bayh-Dole, the Government retains a nonexclusive license for its own use for any subject invention. There are points of intervention for the Federal Government if the broad goals of the act are not being met. However, they are few and rarely exercised.

The exceptional circumstances determination and march-in rights. Within the broad goals of the act, there is encouragement to work with small businesses and to prefer domestic manufacturing. There are also clear admonitions to avoid costly administrative procedures. The Bayh-Dole Act has transformed the nature of Government involvement in patentable inventions, a transformation that we applaud.

By most estimates, the act has led to 1,000 new companies and the creation of about 100,000 new jobs.

The biotechnology industry continues to expand. In 1993, indications are that such inventions generated nearly 3,000 licenses and options, a vastly different situation from 1980, when the Government owned 30,000 inventions, but it had only 5 percent of them patented.

Clearly, the Bayh-Dole Act is providing a positive national economic benefit with its multiple incentives for grantee institutions to move products into the marketplace. The report of the Inspector General addressed many of the specifics about how the Federal

Government can and should monitor the many steps that follow the disclosure of an invention.

The NIH agrees that our monitoring process can be improved and we are taking steps to do so. Staff have been reassigned and the invention reporting function has been brought under our government reinvention laboratory to ensure that we not only have a workable system for invention reporting, but one that interfaces with the other points of contact that NIH makes with the extramural community.

The NIH is implementing a new invention status reporting system that will improve and expand the invention disclosure database and permit the generation of regular reports. It will electronically link our grantees and contractors to our database as part of our electronic research administration program, and the system will generate followup queries to institutions and move smoothly from an invention-by-invention reporting at the early phases to an annual reporting by institutions at a later date, as is detailed in the written testimony.

This system has evolved from a paper-based case record system to one that we think can be more analytically useful. I believe that our present approach will satisfy the needs of the Federal Government, expectations of the Inspector General, and the needs and the capabilities of the many institutions with which we deal. This will make invention reporting part of the network of contacts between the NIH and institutions with which we do business. The act allows for periodic reporting, but it does not envision a detailed followup on the part of the Government. I believe we can meet the intent of the act.

This system will be enforced by our collaborations with other Federal agencies through the Federal Demonstration Project. We would want to vet any new plan for monitoring through other agencies to ensure that institutions could work within a consistent Federal policy. We have asked that this be placed on the agenda for the fall FDP meeting, and there are several alternatives that can be discussed at that time.

In calling for monitoring by the Federal Government, the act envisions such collaboration. For example, the Commerce Department has issued the regulations that govern all Federal agencies, and they serve as a point for complaints. The NIH is also a member of the interagency group chaired by the Department of Commerce to address policy issues regarding Bayh-Dole.

How do investigators and institutions know their rights, their obligations and what is expected of them under the act. Each grantee or contractor is required to inform us of an invention in a timely manner. This requirement also appears on each application for new funding, each application for continuation of funding, and the final closeout of the grant. On each such occasion, the institutional official must report either that there are no inventions, or list them.

While we have a two-pronged approach, whereby we gather data, we are not satisfied that it functions as well as it could. On that point, we agree with the IG. To compliment improvements in the NIH system of reporting and monitoring, a most important focus is education of investigators and grantee institutions where much of the responsibility resides for ensuring that information is trans-

mitted. In those cases where we have contacted institutions to determine the adequacy of their reporting, we have met no resistance.

We have observed some confusion over just what needs to be reported, when, and how. We intend to address this through increased educational activities. In the past, we have used many channels of communication, such as the "NIH Guide to Grants and Contracts," which admittedly goes to 37,000 people on a weekly basis. However, we believe we can do more. We can increase that. We will put it on InterNet through the Gopher system. At present, the "PHS Grants Policy Statement" includes the reference to the regulations, the Commerce Department regulations, but we are requesting that it include the entire regulation. We will also put the regulations on InterNet to ensure that it is easily available to those who need to understand it.

In meeting with representatives of several Federal agencies, we have learned that most agencies prefer education of the entire community and improved dissemination of information over a primarily regulatory approach. This affirms our view that the act's placement of incentives makes it feasible to rely largely, but not exclusively, on education and monitoring for implementation of the act. We believe this is feasible because the act ensures that incentives are properly placed.

For example, it is in the best interests of the inventor to include the Government-use clause, because it makes the title clear when seeking a license. The inventor stands to profit, both in money and prestige, from patenting and licensing and therefore the person most knowledgeable about the sources of funding and the invention itself, as well as the subsequent marketing, knows there is governmental redress if an invention is not being fully developed following licensing.

The small business preference is widely recognized and the growth in small business, which has been spectacular over the last decade, especially those who have ties to the NIH, ensures there is a knowledgeable cadre of small businesses with whom to license inventions, and we see almost a natural affinity growing out from the institutions to small businesses.

It is important that the Government-use clause be included where appropriate, and that other features of Bayh-Dole be addressed. However, the Bayh-Dole Act envisions a cooperative spirit, not an adversarial one. The act was addressing a situation of a great deal of Government control, controls that seem to stifle the movement of products to market. We take a broad view of what the act was intended to accomplish and how it was envisioned working, and we believe that it has been successful. On the other hand, we do agree with the need for improved education and an improvement in our monitoring system, and we are committed to them both.

In regard to the Scripps Research Institute, like the OIG, we are concerned about the underreporting that we have found on a number of patents that have been developed with Federal support. Within the last year, Scripps has updated their reports to the NIH and we believe that Scripps has now accurately reported to the NIH all patents that were developed with Federal support. We have surveyed a sample of institutions to assess whether this may

be atypical or not. We do not have the results of that yet, but we have taken very specific steps, much consistent with the IG report, to determine whether, in fact, this case has been typical or atypical.

In conclusion, we are taking specific steps to improve our own capacity to monitor invention reporting, and we will work closely with the research community to further improve compliance with the provisions of the Bayh-Dole Act. The success story we think is in the fact that research results are being made available to the American public, and they are not languishing on the shelf. We would like to ensure that as we look for ways that we can improve the understanding and the requirements of Bayh-Dole and our ability to obtain and process information about that, that we keep the whole picture of what the Bayh-Dole Act was intended for into perspective.

This completes my testimony, and I would like to answer any questions that the committee might have.

Chairman WYDEN. Dr. Baldwin, thank you.

[Dr. Baldwin's statement may be found in the appendix.]

Chairman WYDEN. Mr. Grant, would you like to make any remarks at this time?

Mr. GRANT. Not at this time. I will be glad to answer questions.

Chairman WYDEN. Very good. Dr. Beers, welcome.

TESTIMONY OF WILLIAM H. BEERS, SENIOR VICE PRESIDENT, SCRIPPS RESEARCH INSTITUTE, LA JOLLA, CALIFORNIA ACCOMPANIED BY DOUGLAS A. BINGHAM, GENERAL COUNSEL

Dr. BEERS. Mr. Chairman and members of the subcommittee, I am William Beers and I am a senior vice president at the Scripps Research Institute, and with me this morning is Douglas Bingham, who is our general counsel.

We welcome this opportunity to speak with you about the report of the Inspector General concerning invention reporting of Scripps and to share with you Scripps' thoughts concerning invention reporting by nonprofit research institutions.

Scripps is one of the world's largest nonprofit, biomedical research organizations not affiliated with a university, and we are flattered that the Chairman has characterized Scripps as one of America's biomedical research crown jewels.

Scripps receives financial support from a number of sources, including individuals, foundations, pharmaceutical and other companies, and, of course, the U.S. Government. Last year, Scripps' funding under grants from the NIH totaled approximately $74 million.

In March 1993, the subcommittee's Chairman and the Ranking Minority Member asked the Inspector General of the Department of Health and Human Services to audit the patents issued to Scripps during the previous 10 years to determine whether Government sponsorship of the underlying research had been duly reported. Scripps cooperated fully with that investigation and with the NIH's inquiries into invention reporting by Scripps. We now believe that Scripps and NIH agree on the status of each of Scripps' patents covering NIH-funded inventions.

The Inspector General found that Scripps had failed to include sponsorship statements required by the Bayh-Dole Act in 43 pat-

ents. We accept this finding and acknowledge these errors of omission. We assure you, however, that these errors were just that—inadvertent, unintentional mistakes. Scripps derives no benefit from omitting sponsorship statements, and we shall soon discuss, we are pleased that the Government suffered no injury from these omissions.

Scripps is committed to ensuring that such mistakes do not happen again. Indeed, even before the Inspector General's investigation began, Scripps was conducting a comprehensive review of its invention disclosures and patents.

As a result, by June 30th, 1993, Scripps had addressed all of the deficiencies described in the Inspector General's report by adding sponsorship statements as required by the act and providing NIH with a complete set of documentation for each existing Scripps patent covering an NIH-funded invention.

The report questions whether sponsorship statements should be added to any of the 35 Scripps patents that do not now contain them. Scripps believes that each of these inventions either was made without Government funding or that no sponsorship requirement was required for other reasons. The PHS comments on the report indicate preliminary agreement with our conclusion as to 33 of these, and last week we reached agreement with NIH as to the other two patents as well. This means that there are no longer any questions between Scripps and NIH regarding which Scripps inventions were made with Government funding.

The Inspector General's only other comment regarding Scripps inventions is that before June 1993, NIH did not have disclosure records for 22 NIH-funded inventions for which Scripps had obtained patents.

Because we do not have access to NIH's records, we can't comment on what they might contain. However, we reviewed our records against a list of Scripps patents provided to us by the IG's office. Our comparison suggests that of the 21 patents on the list, Scripps had submitted disclosure to NIH corresponding to all but 6 of them. Thus, while Scripps may have patented some Government-funded inventions without disclosing them, we believe that such mistakes were made in a relatively small number of cases.

In retrospect, it is clear that we at Scripps have done better at making inventions than reporting them. The regulations that govern the reporting of Government-funded inventions are complicated. There are many requirements and fairly rigid time periods in which to meet them. Perhaps some of Scripps' deficiencies could have been avoided if we had devoted greater resources and attention to our Office of Technology Transfer. However, our records of compliance appear to have improved over the years and we are taking additional steps to improve our compliance in the future. We certainly regret the past deficiencies in our invention reporting.

Fortunately, we believe that our mistakes did not harm the Government or the public in any way. The Bayh-Dole Act gives the Government certain rights with respect to inventions which grantees retain title. These rights could not be lost as a result of belated disclosure by Scripps or failure to include sponsorship statements in certain patents. One purpose of the sponsorship statement is to

notify the Government that it can invoke certain provisions of the Federal Acquisition Regulation, or FAR, which ensures that when the Government buys products, it does not pay royalties for the use of patented technology for which it has a royalty-free license. Scripps' statements were not improperly omitted from a single Scripps patent governing a commercially available product. Thus, we are confident that neither the Government's nor the public's interests were prejudiced in any way by the mistakes Scripps made in reporting its inventions.

Scripps not only has corrected its past mistakes in meeting the Bayh-Dole Act obligations, but it has also taken a number of steps to minimize the risk of similar areas in the future. First, Scripps has begun to account for all invention-based disclosure on a monthly basis. Second, Scripps has begun providing disclosure and other required documents to NIH in a single package every month.

Third, all Scripps patent applications are now reviewed and approved by at least two administrators familiar with Bayh-Dole Act requirements.

Fourth, Scripps has expanded the briefing provided to new faculty members to ensure that they fully understand applicable invention disclosure requirements.

Finally, Scripps will do an internal audit on an annual basis of its compliance with the Bayh-Dole Act requirements.

The Chairman's letter raises a number of more general questions about invention reporting. We must note that Scripps' expertise is in science, not in Government, but with that caveat, we will be pleased to share our views on these matters.

As to how widespread the problem of noncompliance with the Bayh-Dole Act reporting requirements may be, we have no factual basis for drawing any conclusions. The only information that we have, other than what we have heard this morning, is anecdotal from press accounts and that information suggests that inadvertent errors like ours are not uncommon. However, we would defer to others for a more informed response.

The Chairman asked our views on oversight of invention reporting compliance by NIH grantees. Although we claim no expertise in regulatory enforcement, we believe that the NIH and not some other agency should oversee compliance by NIH grantees. They are probably the only agency with the scientific expertise necessary to evaluate and track disclosure filed by its grantees. We recognize that NIH's Division of Extramural Invention Reports has been criticized for its oversight of grantees. When one considers the division's workload, however, we can certainly understand why the division might have encountered problems.

Our written statement includes a number of general suggestions for improving invention reporting practices. We might conclude our remarks today by mentioning a few of these.

First, grantee institutions would benefit from NIH-sponsored workshops instructing Office of Technology Transfer personnel in reporting requirements and suggesting respective procedures for ensuring compliance.

Second, increasing NIH staffing would allow it to oversee compliance more effectively. Finally, it would be useful if grantees could file required documents electronically.

Mr. Chairman, we hope you found this information useful and we would be happy to answer any questions you might have.

[Dr. Beers' statement may be found in the appendix.]

Chairman WYDEN. Thank you very much, Dr. Beers, and we appreciate it.

Let me begin with the gentleman from Texas.

Mr. COMBEST. Thank you, Mr. Chairman. I think it is important to, obviously, to have pointed out some of the past failures and obviously those efforts that are being taken to prevent these from happening in the future. I don't want to overblow this whole issue in terms of suggesting, or I don't want there to be any implication about there being a concern of intentional oversight and fraud or anything of that sort.

I think that this, to me, seems to be one of those situations that is sort of the result of an area that hasn't been of extreme importance—well, not lack of importance, but extreme interest by the fact that there has not been—there has been a very small record of any need for NIH or for Government to step in and stop some of the pricing policies or the march-in opportunities that could have been exercised under Bayh-Dole. This is just one of those things that has never been on the top shelf as far as importance and significance.

Also, I think it is important to recognize that the role of NIH has been to—in the use of its limited, resources has been to try to come up with new technologies, with new procedures, with new medicines, and that should be the goal. I would not want this to either create a huge additional, unnecessary burden on NIH, on Scripps or on anyone else who is involved in this, I think, this is a very important process, and that the American people have benefited greatly from it. So, I think that if we can—I do believe there is a way, and possibly Mr. Skelton's suggestions earlier might be worth looking into to try to determine if there is a way to accomplish the goal at a minimum amount of number one, regulation, and paperwork, and time spent both in terms of hours and in terms of money, to try to make for sure that everyone is in compliance. That would be my goal to see if there is some way that we can attain that, and given that this has become an area of considerable interest, you have all looked into it fairly closely, and I would think your suggestions in how we might be able to reach that goal would be important.

Dr. Baldwin, you had mentioned in your testimony relative to—you referenced small business, that there was growth, there has been additional involvement of small business. What is the definition—how do you all define small business? Is it the standard Government definition?

Dr. BALDWIN. Yes.

Mr. COMBEST. I am sorry?

Mr. GRANT. It is based upon the Small Business Administration guidelines.

Mr. COMBEST. Do you have an opinion on what the gentleman from Missouri, Mr. Skelton, had mentioned earlier about, as the process was moved forward to patent, that there might be a disclosure at that point? That would seem—I like that idea from that direction. I don't want to transfer the regulatory authority to some

other agency, but at the same time that would seem to be a fairly easily accomplished goal, and if there is a connect between any other Government monies beyond just NIH in which a company was applying for a patent. That might be a fairly simple way to achieve that goal. Do you have any comments on that?

Dr. BALDWIN. Yes, actually, I do. That is something we have already been discussing, because while it is required now, we would like to look at any ways that could be undertaken that would strengthen that request, that would highlight that request coming from the Patent and Trademark office.

For example, reference to fraud and civil penalties in the response to those questions, as you point out, this is not just an NIH issue. The question here is all across Government. We are very mindful of the fact that we don't want to develop strategies that might, in fact, look fine for the NIH, but in fact, really do apply more generally or should apply more generally. We are trying to do things that can be done in concert with other agencies and that will provide one simple point of entry for those on the outside and also some consistency that meet all of the goals on the inside for the Federal Government as well.

I think that you and Mr. Skelton both have really focused in on something that could be a constructive step right at an appropriate point that doesn't create an undue burden, that does not create additional paperwork, and that, in fact, would have a very material benefit. That is a point of intervention. I think that is a point of intervention that we have been discussing that is one that we think perhaps could be heightened for very good outcome.

Mr. COMBEST. The tree or the trigger point is at the patent, at the time of patent.

Dr. BALDWIN. Yes, that is right.

Mr. COMBEST. In other instances where there have been other monies involved, but where there has been no pursuit of that, that obviously would come into play, so that trigger point would seem to be applicable to all agencies and to all individuals who have used Government and grants in research that might have—that would be susceptible to this.

Dr. Beers, do you have comments on that? How would that impact you from your sector?

Dr. BEERS. That would be no problem for us. I think that it actually moves things in a constructive direction. Part of the problem that institutions have in meeting all of the requirements of Bayh-Dole, is that there are many notifications required, and that there is some lack of communication sometimes within the institution with lawyers and so forth so that things can fall through the cracks. Often those involve disclosures that may never become patented. So, if you had a system that required you at the time of patent to notify, then that, for us, would be a step in the right direction.

Mr. COMBEST. Yeah. I don't know, sometimes when the Government does things, they don't always do it the simplest way. But it would seem to me that that would be a fairly easy step to accomplish, so that the appropriate agency would be notified at such a patent application time, whether it was NIH or whoever it might be, depending on the source of the patent, that was a really good

idea that I think that you have been looking into and that Mr. Skelton had because it would seem to accomplish the goal.

We need to look into it further to see that—it might not be quite as simple as it seems. But it would seem to accomplish the goal with a minimum amount of additional burden. My goodness, this subcommittee is a Subcommittee on Regulation, and we have an overburdensome regulatory atmosphere on business out there today, and I would be the last that would be drug screaming and kicking to the trough to impose more. But I think that seems like a very workable solution, because there are a lot of taxpayer dollars involved here. But again, there is no implication that these have been misspent.

I think what it really shows is a great amount of Federal dollars that have gone into some very worthwhile causes. I think we have pretty much established already the fact that this is much widespread beyond just Scripps. But are there further thoughts or comments, Dr. Baldwin, that you would like to make in terms of how far-reaching it is, as you have been able to look into it, to determine the—beyond just Scripps, how extensive this problem might be?

Dr. BALDWIN. We just don't know yet. We have a project underway where we are going to look at some institutions where they have a high volume of patient activity. We are looking at some where they have a low volume, because, in fact, institutions reporting a low volume might be those that are having the most difficulty understanding and interpreting when they have to include the clause and when we would need to know about them. So, it is not just enough to go to those who seem to have high volume. We are doing more of them, but we are also doing some of the slower volume ones as well.

After we have done that, that first pass through them, I think we will have a much better idea as to how widespread this might be. We do feel that the educational activities have to take place regardless, because there is a level of misunderstanding, and as Dr. Beers has pointed out, these are in some cases confusing regulations, and there are some cases where they seem to have multiple points of contact, and we feel that we can probably have the biggest impact if we work through the next coming round of meetings with organizational officials and increase that information that we can get out there. I think after we do that and after we do this first pass of review of other institutions, we will have a much better idea of how widespread this is, and then what steps we might have to take next.

Mr. COMBEST. Well, I think, Dr. Beers you are missing this inadvertently, I think inadvertently and certainly there were no negative consequences which arose from it. I would hope that in those cases where there are problems among other institutions or recipients, grant recipients, that is the same case.

My concern would be how significantly if in your investigation you find that it is not the case, that there was an intention for some reason, and I think that I would not be quite so inclined to just sort of pass over this, but I—in the case of Scripps, I appreciate your mentioning the fact that it had been inadvertent in the

past, and I am going to have a positive attitude about this and assume that that is going to be the case in the other instances.

I appreciate the time, Mr. Chairman.

Chairman WYDEN. I thank the gentleman. Let's begin with you, Dr. Baldwin. Let me tell you, it sure seems that there is a big gap between how you see this matter and how the Inspector General sees this matter. The Inspector General talks about how there is one person there when there used to be two. The Inspector General says that there are fundamental problems existing with NIH's monitoring ability. The Inspector General says that the NIH lacks information to ensure compliance with the laws and regulations. You seem to be just warming things over a little bit, and just keep doing what you are doing. So, let's start by examining the matter at Scripps.

My understanding is Scripps has been a grantee of the National Institutes of Health just about since the enactment of Bayh-Dole 14 years ago. Do you have any idea how much Federal funding Scripps has received in that time period?

Dr. BALDWIN. Well, I believe since the last 10 years, it is in excess of $500 million.

Chairman WYDEN. My understanding is about $1 billion since the act went into effect. Is that right, Dr. Beers?

Dr. BEERS. Since the act went into effect, which would be 14 years ago.

Chairman WYDEN. Right.

Dr. BEERS. I don't have those numbers. Doug, do you? But I think that it is fair to say that the research institute has been receiving Government funding since before the act.

Chairman WYDEN. Right. But I am particularly interested in what has happened since Bayh-Dole. It seems to me that we are talking about close to $1 billion since Bahy-Dole. Yet you are saying, Dr. Baldwin, that this institution and others as well, given your remarks, it is reasonable for the people in this country to believe that it was just too confusing for them to notify the Federal Government when they got a patent as a result of a federally funded invention. Is that correct?

Dr. BALDWIN. Well, perhaps I should go back to the issues that the Inspector General concluded with, because, in fact, I think there is a great deal of agreement between our position and the Inspector General's position.

Chairman WYDEN. Before we do that, let us address this one question. You have indicated that institutions are confused.

Dr. BALDWIN. Yes, I believe that.

Chairman WYDEN. They don't know what is expected of them. We are talking about an institution, that as far as I can tell, got close to $1 billion. We are talking about other institutions that receive vast sums of money. The statute has been in effect for 14 years, and you are saying somehow it is too confusing for an institution to let the Federal Government know when the institution gets a patent with Federal funds; is that correct?

Dr. BALDWIN. I believe institutions could be doing a much better job in informing us of inventions, and a great deal of that responsibility lies with the institutions to make sure that their employee agreements are clear, and a great deal of that responsibility lies

with us to ensure that we have a system in place for them to report to, that we have a system in place that we will be able then to use for more analytical purposes as opposed to simply generating a case file.

I am not saying that there haven't been any problems in the past. There have been tremendous problems. My points of agreement with the Inspector General lie around what our current status is and what our plans for the future are. I believe that we do, in fact, have a very constructive plan for the future. In regard to Scripps, I understood the Inspector General to say that we should reconcile all of those cases, and I believe that we have.

In regard to the other institutions, I understood that the concern was that we find out whether in fact, the situation with Scripps was atypical, or whether, in fact, it was not, and, in fact, we have a project under way right now that will give us that.

I agree that we could work with the Patent and Trademark Office, and especially according to the suggestion from Mr. Skelton that we, in fact, look at a way that they could, in fact, be a much more proactive point for us in terms of ensuring that people filing for those patents do report Government activity, Government funding where it has been. We certainly agree that we have to improve compliance and that our educational strategies are a part of that. I have increased the staffing. We are back to two and we are looking to increase it further.

In terms of staffing, I think it is also important to bear in mind that putting our electronic reporting system into place, which is not just one where we key in information that is sent in manually, but is actually an electronic transfer from the institutions, is critical to both the success of the system and also of the necessary staffing, and I would prefer to reengineer that system first before I focus too much on the staffing that is required there. The primary reporting obligation lies with the grantees, and that is why I feel that the educational component of this is so important.

Chairman WYDEN. Again, the Inspector General said that the central problem is that you are still going to run a voluntary program. The Inspector General has made it clear that when you are talking about $8 billion that we ought to have something a little bit more than a kind of discretionary, voluntary, trust us kind of operation. Let me ask you some more questions about the Scripps issue, and then we will talk some more about the system.

Dr. BALDWIN. OK.

Chairman WYDEN. I wonder if you could comment about the distortions in data between, one, what the NIH apparently knew about Scripps' inventions at the beginning of the audit; two, what Scripps told the Inspector General at the beginning of the audit; and three, what Scripps said in the way of a revised estimate at the beginning of the audit. Excuse me, at the end of the audit.

Now, basically the National Institutes of Health thought that the number of Government-sponsored inventions was about five. At about that time, the Scripps Institute said it was about 51. Finally, a year after the audit began, Scripps says, oops, made a mistake here. It looks like it is close to 94. This is just a misunderstanding of the law and of the requirements. It is just kind of hard for me to understand how it can be so complicated after 14 years, at an

institution that receives vast sums of Government money, and other institutions apparently. Given your statement, how it can be so complicated for these institutions to notify the Federal Government when they get a patent that was obtained to some extent with Federal funds? Am I missing something here? What is so complicated about all of this?

Dr. BALDWIN. Well, I think the question of when an investigator and their institution understand that the work, in fact, meets the definition of the Federal funding for an invention of something first conceived or brought to practice, perhaps that question is better addressed to the gentlemen from Scripps who are on the frontline with investigators who are trying to, in fact, understand those rules. I will say that our system has not been adequate to ensure that we had the information in from the institutions, and that we were processing it in a meaningful way, and we are taking steps to change that.

Chairman WYDEN. Doctor, if you would just clarify us with respect to the law. If an institution gets Federal funds and they do research and that research leads to an invention that is patented, does the law say that you have to notify the Federal Government about that patent?

Dr. BALDWIN. Yes, it does, sir.

Chairman WYDEN. I must tell you, I am just baffled about how you and others can say that this is such an extraordinarily complicated task. I mean either one gets a patent or one doesn't. Either one gets Federal funds to do research, or one doesn't. You all have in effect, come to the subcommittee and somehow have, I think, tried to convince me that this is rocket scientist material. But my sense is either you get a patent or you don't; either you get Federal funds or you don't.

The law seems to say clearly that if you file a patent on an invention which was done with Federal funds, you got to notify, and maybe clarify for me why all of this is so complicated to you.

Dr. BALDWIN. Well, I think some of the explanation comes from the fact that there are ways that an investigator and an institution could be receiving Federal funds, but where it does not fit under the definition of first conceived or first reduced to practice, such that there would be Federal funding surrounding work that is involved with an invention, but it might not fall under that definition. I think certainly if we look at a clinical trial, we may see vast amounts of money going into work related to a drug, but that comes in after a patent and it has no bearing on it. So, it is not quite as straightforward as I think we would all like it to be. It would make my job a lot simpler if it were.

Chairman WYDEN. Well, two out of three dollars used by this institution seem to come from the taxpayer.

Dr. BALDWIN. Yes.

Chairman WYDEN. We are going to review the areas that you seem to feel are so complicated. However, I can tell you, the Inspector General doesn't think this is that complicated. When I asked him, the Inspector General said that he didn't think there was a great burden in setting up a computerized system that would file the reports establishing the taxpayers' interest electronically. He also said that the Patent Office could be involved in this, and in

some instances, he said he picked up on this kind of information which you say is so complicated and burdensome in a few hours. I think we have real differences between how you and the Inspector General see this issue.

Let me ask you again about Scripps. You say that you believe the problems at Scripps have been settled because you wrote them a letter 5 days ago and asked them to either certify to you that there were no other patents developed with Federal support during the period of review that should have been reported or report any additional patents that were not previously reported.

Now, this has been their legal obligation as far as I can tell since 1980. If that obligation had been properly met over the last 14 years through voluntary action, how do you expect a call 5 days ago for voluntary action to work now?

Dr. BALDWIN. Well, we have certainly been, as you have already explained, we have certainly been on an unfolding process of trying to reconcile our records. So, this is not something that had to be done overnight. If we felt that there were malicious intent, if we felt that there were an intention on the part of Scripps to suppress this information, that would be a different situation. But that has not been our experience. Our experience has been one of trying to work out the common understandings on the need for the paperwork and to get it communicated. We feel that we have been able to do that. This is what gives us some confidence that we would be able to do this with other institutions.

I certainly hope that establishing electronic transmission of data is going to be relatively simple, because that is the strategy that we would like to pursue. That takes care of one part of the problem, which is us getting information and dates once it is known and understood. The educational component takes part of the knowing and understanding part, and we have to have both parts of it.

Chairman WYDEN. I am also a little bit puzzled on how you can say that there is good intent here, just because Dr. Beers, who is a fine fellow and Scripps, which is an outstanding institution says so. What we have is a situation based on 70 to 80 inventions that Scripps failed to disclose over the decade, largely were not commercialized, and nobody really picked realized it. I am wondering how you can say that everybody's intent is good, when we have virtually no information on much of what has gone on during this period.

Dr. BALDWIN. Well, we have been able to reconcile records at this time.

Chairman WYDEN. So you have been able to go back and reconcile all 14 years worth of records. The records that the Inspector General said were in disarray have now been reconciled. Therefore, on the basis of that work 5 days ago you can say that things are in good shape now?

Dr. BALDWIN. They are reconciled. I don't know that I would say that our record systems are in good shape yet.

Chairman WYDEN. The IG has recommended that there be an audit of the other 30 patents. It seems to me that maybe things aren't quite as hunky-dory as you say. What do you think?

Dr. BALDWIN. I don't feel at this time that an audit of those further records is necessary, but I would be certainly happy to discuss it further.

Chairman WYDEN. Now, doctor, you stated that the NIH has exercised its march-in rights in several occasions. Could you give the subcommittee some examples?

Dr. BALDWIN. No. I am sorry, I couldn't.

Chairman WYDEN. Could you provide that for the record?

Dr. BALDWIN. No, I am sorry, we have done exceptional circumstances, but not march-in. We have had the right to do march-in, but we have not used it.

Chairman WYDEN. Tell us about those kinds of situations, which is an area where I think the language is a bit confusing. Tell us about the exceptional circumstances situation.

Dr. BALDWIN. Well, exceptional circumstances covers a situation whereby allowing a contractor to have title, if they are doing the screening of drugs, would give them an inappropriate role in ultimate and further patenting of information, where they are actually providing a service and a screening for us. So, we have that tool. We have the march-in option, if, in fact, we find a situation that is egregious, if we see a situation that is not being taken to market. If we have a problem case, we have a tool to use.

Chairman WYDEN. Well, to make use of this tool, you must have the information. Your agency has been consistently in the dark, and that, I think, is the conclusion to which we keep returning. I am glad that you are saying that the tool is a useful one to you, but unless you get the information, you can't move to the next tier of using your tools.

Now, the Government has granted a nonexclusive license under Bayh-Dole to any patented product developed under Federal grant dollars. Generally, this means that the Government is not required to pay the royalty that is always included in the price of the product. Has the NIH purchased any product on the open market that was developed using NIH grant funds?

Dr. BALDWIN. The NIH use of commercial products is frequently for continued research use. In many of those cases, we, in fact, obtain those materials without cost or at greatly reduced cost. I do not have a specific example of where we obtained it exactly royalty-free, but with no other price consideration.

Chairman WYDEN. Why don't you provide that for the record as well.

Dr. BALDWIN. Certainly.

[The information may be found in the appendix.]

Chairman WYDEN. You said that you all were back up from one to two. We are glad to hear about that in terms of staffing arrangements. Can you tell us what kind of paperwork volume there is at the Extramural Invention Reports Office?

Dr. BALDWIN. Since that office reports directly to Mr. Grant, I would like him to answer.

Chairman WYDEN. That will be fine.

Mr. GRANT. Sir, we are receiving approximately 2,000 individual reports a year. That would be invention disclosures. The law also requires then that we follow up to make sure that those disclosures are subsequently being applied for, or that the institution is

waiving its rights in those interests. Then following that, the patent may be issued.

The interest here, of course, is that the Federal rights clause is also provided. Given that volume of reports that we feel that the electronic system of reporting will help facilitate this both for recipient organizations as well as for the NIH. That system can also generate queries, have followup responses for NIH, and so forth.

Chairman WYDEN. Dr. Beers, are you saying that the National Institutes of Health may have lost some reports that came from your program that would have indicated a better reporting record on the part of your institution than otherwise would be indicated?

Dr. BEERS. It is my understanding that we had some receipts, receipt of documents that the NIH didn't report that they had.

Chairman WYDEN. How do we reconcile this, Dr. Baldwin?

Dr. BALDWIN. We believe now that we are in receipt of everything that was sent by Scripps. We have been doing a rather exhaustive review of everything in invention reporting, and that is no longer a problem.

Chairman WYDEN. Well, I am glad to hear it is no longer a problem. For taxpayers who watch their dollars get used in this fashion, we have a situation where your agency initially said that they had five inventions according to their records, and then it went to 50 on the basis of Scripps, and then it went up to 90. I am wondering perhaps—Dr. Grant, you may answer as well—whether this is an indication that maybe the agency is just getting too much work put in front of them with too few resources?

Mr. GRANT. Well, the important thing, sir, I think the review by the Inspector General has demonstrated that the area deserves a lot of attention and we are providing that. I am confident now that given our improvement in the system and the resources that we are providing, that we can address those requirements, and along with the suggestion made by Mr. Skelton, I think we can provide very important assurance in the process. We have also considered that at the time we request from institutions an annual report of all of their patent activity, that we also receive an assurance from them that would affirm that there were no other inventions or patents that have been developed in the past year. Such an assurance that is not in place now.

We feel that that type of reporting system would provide an annual audit, if you will, by institutions of their patent activity, and that will provide an important confirmation of the various rights of the Federal Government in this regard.

Chairman WYDEN. Let me make some additional requests of you, if I could, Dr. Baldwin. We would like copies of your responses from the 20 institutions you have contacted in your attempt to reconcile your records with theirs. Could we have a copy of that?

Dr. BALDWIN. Yes.

[The information may be found in the appendix.]

Chairman WYDEN. We would also like to see any correspondence you have with the five institutions you say report few patents with Federal support, even though they are among the top 100 recipients. Obviously, in both of these matters, we would work with you to ensure confidentiality and protections.

Chairman WYDEN. Finally, it would be instructive for your agency to compare the number of patents issued to the five institutions which are co-owned by corporate donors and partners, particularly as a comparison against the number of patents which are identified as having had some Federal support. Is that something you could look at for us?

Dr. BALDWIN. We will certainly look into that.

Chairman WYDEN. Let me wrap up by looking again at the voluntary nature of the system, so we can see if maybe we can nail this down.

If you have a computerized system that files reports establishing the taxpayers' interest electronically which you used via assistance of the Patent Office what is wrong with just requiring it as suggested by the Inspector General rather than making a kind of wish list, trust us, hope-it-all-works-out kind of arrangement the way we have now?

Dr. BALDWIN. Well, the issue is not just whether there is a patent, the issue is whether, in fact, upon inspection it was first conceived or first reduced to practice under Federal funding. So, unfortunately, it is more complicated than simply determining that a patent is there. I would be pleased to use the data from the Patent and Trademark Office on an investigational basis, if we have an unusual case, to use that to see if we have specific patents that we should be pursuing.

I think that, in fact, could be a valuable tool. I wish this were not as complicated as it is, and as difficult as it is to go back to determine whether or not it should have been disclosed to us. But that, unfortunately——

Chairman WYDEN. We think that the issues that you are raising are very legitimate ones. What is wrong with having a real trigger rather than one that's voluntary. Therefore, when the real trigger goes off, can you go out and do the work that you need to do in some of these areas that do not seem to be so black and white?

Mr. Skelton and I are essentially talking about the same thing. That is having a real trigger, something that goes off automatically, involving the Patent Office and a computerized system. During the 1990's. Not going back to quill pen days where you have to have people sitting around for days recording all of this stuff. We will move on here, but I hope that you will examine that closely because that seems to me to be the way we are going to get our arms around this. It is not going to be accomplished on a voluntary basis. The issues that you indicate need to be pursued strike me as very appropriate issues for the agency to pursue, and they certainly fall into the gray area. What is not gray is the idea that when somebody gets a patent, and you have a law that has been on the books for 14 years. The reason that the law is on the book is that the taxpayers have basic interests here. We will be following this up with you some more, but I hope that you will look at the idea of having a real trigger rather than this voluntary system. The Inspector General says the current system is inadequate. I believe it is inadequate, and I think this subcommittee believes it inadequate as well.

Let me ask a few questions of Dr. Beers. If we can keep you, Dr. Baldwin and Dr. Grant, at the table, that would be helpful as well.

Dr. Beers, if we might, some general agreement on the numbers involving your institution. When going through the Government disclosure records, the IG found that the NIH had record of only 13 inventions issued to the Institute. Of these, only five were noted as having had Federal support.

When the Inspector General went to Scripps seeking the same information for that time period of 11 or 12 years, Scripps said initially that it had been issued 125 patents and that 51 had some Federal involvement. Later, after a number of questions were raised by the Inspector General, Scripps said an additional 43 patents apparently had some Federal involvement. That is a total of 94, of the 125 patents issued to Scripps. Is that approximately correct?

Dr. BEERS. I can confirm the last three numbers. I am not sure about the first two, but I will ask Mr. Bingham.

Mr. BINGHAM. Those are based on NIH records. We have no idea what they actually had in their files.

Chairman WYDEN. So most of the numbers are correct. Now, Dr. Beers, you say that this technology was not reported because of errors; inadvertent, unintentional mistakes. Now, certainly everybody has made mistakes and this Member of Congress made plenty of them and everybody has as well. The proposition that Scripps is not disclosing dozens of these inventions paid for by the taxpayer. Your view is that lots of other institutions were there as well in essentially the same kind of boat. But my question to you is how did it happen that this system, which now has been out there for 14 years, has in effect, pushed out the door of Washington, DC, billions and billions of dollars, has gone on for so long in a fashion that seems to have, I guess, as the Inspector General really says, produced broad-scale, significant, essentially, pattern of underreporting.

Dr. BEERS. With all due respect, Mr. Chairman, I would like to clarify what you are talking about. I believe the 43 refers to a notification, a legend on the patent that indicates there was Federal money, not a disclosure.

Chairman WYDEN. Correct.

Dr. BEERS. Let me go through the process for you. I can't explain it and say it should have happened. It shouldn't have. But I think you can see that a lot of things go on.

First, the scientist must come forward with a disclosure. That disclosure gets sent to the NIH and Scripps must elect to retain title. That also goes to the NIH. Scripps then applies for a patent and that must go to the NIH. Then finally when the patent is issued, that also goes to the NIH. The time span between the disclosure and the issuance of the patent can be up to 2 years, and I think it is fair to say, or at least it is my understanding, that most of our errors occurred in the early years of Bayh-Dole. Second, at that time we were using outside counsel who took a policy that they would not legend a patent until the patent was issued and they could be sure that, in fact, what the patent was about was covered by Federal funds.

There were clearly some times when that ball got dropped, when the patent was issued, the legend didn't get put on. There were some other errors, too, but I think as was in our case, there was

primarily a communication problem over 2 years that sometimes things got dropped.

Chairman WYDEN. So your view is that we got a statute that was 14 years old, but the problems essentially involve just 2 years and that even though most of the patents didn't seem to get reported, it was essentially a 2-year problem.

Dr. BEERS. No, I wouldn't say it was a 2-year problem, it was in the early years. But it was in the first 7 years, clearly when we experienced most of our problems.

Chairman WYDEN. You say, Dr. Beers, that the Government has suffered no injury from these omissions. After having discussed this with folks at Scripps, what troubles me about this is that I am not sure that our country even knows what has been lost that is of value to the taxpayers. We have a situation where so many of these things aren't commercialized. That is the purpose of the statute.

Clearly, if you had the information, you could go back and review some of these kinds of issues. But when you say there has been no injury from the omissions, the Government and the taxpayers are in a position to have to trust you because the country really just doesn't know what kinds of opportunities have been lost that were funded by the Federal Government. Would you like to respond to that?

Dr. BEERS. Yes. We aggressively market our inventions. We try very hard to find some licensee. As you know, we have standing arrangements with organizations like Johnson & Johnson and will in the future with Sandoz, but beyond that we go out all the time to find licensees for discoveries that aren't picked up by large pharmaceutical partners. Beyond that, I don't believe that we have a choice. We can't turn to the NIH and say you license it because they aren't in that business. So, we market everything that we can, and we believe that we are doing a reasonable job of it.

Chairman WYDEN. My understanding is that Johnson & Johnson had something like 85 licenses on products involved with you. Only a couple of them were commercialized. Now nobody really knows why and nobody really has the information because things were in such a shambles all those years.

Dr. BEERS. You mean the Government?

Chairman WYDEN. Yes. How would you respond to that?

Dr. BEERS. Well, we think in many ways that that problem takes care of itself. We track what Johnson & Johnson is doing and more importantly the inventors are very aware of what is going on with their inventions because they stand to benefit personally as well as the Institute stands to benefit. So, they are, I can tell you from personal experience, ever vigilant. The institution is vigilant. So, if we were to see an example of something being shelved or not pursued by whoever the licensee was, we would take back the invention.

We haven't seen that. You have to appreciate there are a number of things in the pipeline at Johnson & Johnson. It takes a long time to deliver these drugs and given the duration of the agreement, you are going to see an increase in the number of products hitting the market.

Chairman WYDEN. Have you ever recalled technologies from Johnson & Johnson, or have they ever turned anything to you?

Dr. BEERS. Doug may want to answer that. He would be more familiar with it than I am.

Mr. BINGHAM. Johnson & Johnson regularly gives back technologies to us that they have not been able to develop or no longer fit their strategic plans and we outlicense them of it. Some of it the technology is just not capable of commercialization. In the drug industry I think you will find that the industry standard is, if you are lucky, 1 in 100 patents covers a product and that is about what Scripps' record is.

Chairman WYDEN. To me, the bottom line, Dr. Beers, is no Member of Congress is disagreeing with your statement on injury. No one is accusing you of perpetrating injury as result of these omissions. But what is serious here is the country doesn't know what has been lost. You continue to say that all of the deficiencies cited by the Inspector General have now been addressed. But isn't it a fact that the Inspector has suggested that all of the remaining patents issued to Scripps outside of the 94 have to be reviewed as well?

Dr. BEERS. We would certainly have no objection to that. We believe that those are not subject to the—requiring a legend.

Chairman WYDEN. When you say everything has been taken care of, and the Inspector General is suggesting that the remaining patents be reviewed as well, it indicates to me that you know that we have more to do here. I just think that we are talking about something that is far more than some inadvertent errors. It is something that the Inspector General, and this is something I obviously want to communicate to you, Dr. Baldwin, and to the National Institutes of Health, that the Inspector General is talking about the potential of a broad-scale significant pattern of underreporting and missing what are very important concerns for taxpayers as a result. If it is business as usual, where there is just a voluntary program and we kind of wish and hope everything comes out fine, my sense is we will be back here before too long asking a lot of the same questions. I am quite certain Dr. Beers does not want to have the same questions posed to him again in a year.

I know enough about you, Dr. Baldwin, that you have many important responsibilities as well, and do not want to have the same questions asked of you in a year. Unless you have anything you would like to add, I will excuse you. We will be happy to have you add anything further, but we have got to turn this around. This is unacceptable.

My colleague, Mr. Skelton, one of the more milder-mannered Members of this body said it very well. If this was going on at the Pentagon, people would be jumping up and doing a lot of hollering. We have got to turn this around because the stakes are too great. The sums of money are too large. We are not talking about an isolated grant. We're talking about something that affects the prices of products for the American people. We're talking about jobs in the United States. We're talking about the well-being of our small businesses. You heard the Inspector General say he thought he picked it up at the University of California and the University of Minnesota as well, in his additional auditing, indicating to me that we have got to turn this around. I am anxious to work closely with the institutes to do it.

Is there anything you would like to add further, Dr. Baldwin?

Dr. BALDWIN. No, just to say that we think we have a plan underway now that, in fact, will turn around our reporting. I do believe that as Dr. Beers has pointed out, there are incentives in Bayh-Dole and that we're not just relying on honor. I would hope that there is honor out there among our grantees and contractors and scientists we deal with, but, in fact, there are also very direct incentives and Bayh-Dole places those incentives where we know that there are others out there that also have a concern to see that these products get to market. That has been a feature of how it has been implemented so far.

Chairman WYDEN. Make no mistake about it, Dr. Baldwin, we believe that the vast majority of scientists and grantees are honorable and doing good work. But the message ought not to be trust us, but trust and verify, Dr. Baldwin. That is what Congress intended. That is what the taxpayers of this country think they are going to get when $8 billion goes out the door.

So, we have no quarrel whatever with you about the idea that the vast majority of grantees and institutions and researchers are honorable. But $8 billion is too much money and the stakes are too great to not have a program where, in addition to trusting, we do a lot of verifying as well. We will excuse you at this time. We thank you for your cooperation with the subcommittee.

Dr. BEERS. Thank you.

Chairman WYDEN. Our next panel is Mr. James Packard Love, Taxpayer Assets Project of Philadelphia, Pennsylvania; Dr. Michael Davis, professor, School of Law, Cleveland State University, Cleveland, Ohio.

Gentlemen, you are on your feet because you believe that we are about to commence with the formalities and your are correct. Mr. Love, do you desire to have one of your associates?

Mr. LOVE. Yes, this is Mr. Michael Ward. It is the Taxpayers Assets Project, and Michael works in the Washington office.

Chairman WYDEN. A fine organization I might add. We work with them frequently. We have both Mr. Love and Mr. Michael Ward, and Professor Davis is here as well.

You all have no objection to being sworn as witnesses?

[Witnesses sworn.]

Chairman WYDEN. We will make your prepared remarks a part of the hearing record in their entirety, gentlemen. If we could, perhaps summarize your views to get us going and, Mr. Love, let us begin with you.

TESTIMONY OF JAMES PACKARD LOVE, TAXPAYER ASSETS FOUNDATION, PHILADELPHIA ACCOMPANIED BY MICHAEL WARD

Mr. LOVE. Thank you, Congressman Wyden. I would like to thank you for the invitation to talk about an important issue, the degree to which the National Institutes of Health is protecting the public interest in taxpayer-funded research and health care.

I guess by the figures we saw earlier today that amounts to around $25, $26 per capita in the United States, just as, to put it in more practical terms, that is how much money it is per individual that we are talking about in the $7.3 billion.

As you know, we have done over the course of the last several years, first, actually at the request of this subcommittee, looked at a number of issues relating to the Government involvement in the development of new drugs which we think is an important issue, which is part of the issues that I am going to talk about later, have to do with the difficulty of doing the research relative to getting the information from the Federal agencies that are involved in this and from the companies and what we think some of the implications are.

But if I could briefly summarize in a minute some of our more recent findings, in one study which we completed in February 1993, we found that 34 out of 37 cancer drugs that were invented and approved by the FDA since 1955 were developed with significant Federal support. We also looked at over a period between 1987 and 1991, all FDA priority drugs; that is, drugs that are used to treat either severe illnesses or drugs for which represent a significant gain in therapy over existing drugs in the market and over this 5-year period, 71 percent of the drugs approved by the FDA which met these criteria were developed with significant Federal support.

We also found that over the same period in looking at a larger group of drugs, both discovered in the United States and drugs that were discovered elsewhere, but which were approved by the FDA for marketing, that of the drugs in our study that were developed with public funds, the cost of a treatment, completed course of treatment or a year of treatment, whichever was less, was $4,800 for drugs that were developed with Government funding and $1,600 for drugs that were developed without Government funding, meaning that the drugs that were developed with Government funding were priced about three times higher than drugs that were developed entirely with private funding, indicating that the companies were not passing on the benefits of the Government funding to the actual consumers who pay for those drugs.

In the course of our research on the role of the Government if paying for the cost of R&D for new drug development it is nearly impossible to find anyone in most Federal agencies who can even speculate what the public has done for the support of a drug.

Accompanying me is Mr. Michael Ward, a research associate at the Center for Study of Responsive Laws, Taxpayer Asset Project where he does a lot of the leg work in checking these issues out. We have to look at patents, we have studied the scientific literature to track down evidence of Government researchers that were involved or grants that were involved. We have talked with principal investigators. We have talked with the company and we talked to the agency.

When we talk to someone at NIH, university or a firm, the most common answer we have about whether or not Federal funds were used in the development of a drug, the answer was I don't know. Sometimes actually people give us wrong information. For example when we contacted Roberts Pharmaceuticals about the drug, Supprelin, we were told by one of the researchers who had received industry support from Roberts Pharmaceuticals as to the role of the Government in the development of the drug, we were told that there had been no involvement at all.

Two days later, we were able to establish that Massachusetts General Hospital had been involved. Ten years of NIH funded research led to some of the most important discoveries that were used in the approval of the drug. Had we relied upon the initial indications we had from people who were really in a position to know, we would have reached the wrong conclusion. It is just, I think, typical of the kind of detective work that we have to undertake in order to determine whether or not the Government was or was not involved.

Because we have done a fair amount of this research in the past, we are often asked by journalists or other people as far as new drugs coming on the market, which ones is there Government involvement in and they don't ask the FDA or call up the NIH, or if they do, they probably get the same response we have, which is that nobody seems to know or keep track of this kind of thing. It is considered to be not a matter for the Government to keep track and organize this information.

Now, this hearing is focused a lot on the issue of patent applications and we think that this is a very important thing and we applaud the subcommittee's efforts to look at this. We would like to point out, though, that the issue of patent applications only addresses part of the problem.

There are a number of drugs, for example, Ceredase, developed through significant funding through the National Institutes of Health, initially through Tufts University, which was priced for some patients as high as $550,000 for a single year of treatment for which no patent exists and for which the company that is marketing the drug has benefited from a monopoly product under the Orphan Drug Act.

There are other cases such as levamisole, a drug that was marketed by Johnson & Johnson for colon cancer, which some of the crucial research that took place on that drug occurred after the patent was approved, which in the case of levamisole was given to Johnson & Johnson in 1986, which two of the most important studies that were funded by the Government, which led to the approval for the drug in the use of humans for treatment of cancer occurred in 1989, and 1990, after the patent was given.

So, in general, we found that the Government's contribution to research may occur before or after the patent is obtained and so we think that any effort to track what the Government's role is in the development of new drugs has to encompass, in addition to information which is true at the time of the patent, research that occurs after the patent and also research that occurs in cases where there is no patent at all, as in Taxol, Ceredase and many other drugs, particularly drugs which are covered by the Orphan Drug Act, which conveys patent-like powers without the obligation to have been involved in the invention of the drug.

I would like to talk very briefly about the NIH's role in protecting the public. I was really startled to sit here today and to listen to Dr. Baldwin's testimony, which really seemed to minimize the problems that exist relative to the failure of Scripps to disclose its inventions. I was reminded of being here about a year ago and listening to the previous Director of the National Institutes of Health, Dr. Bernadine Healy, actually take quite seriously the problems in-

volved with Scripps, and actually remind members of the committee how important march-in rights were considered. She threatened the Scripps Research Institute with exercising the march-in rights as a way, together with the work that was done by the subcommittee staff and the subcommittee Chairman, to force Scripps to renegotiate a contract with a foreign-owned pharmaceutical company which gave it virtual control and ownership over the Scripps Research Institute and that deal would not have been changed, it appeared to us, had not NIH taken a much different attitude than we saw here this afternoon, which was an aggressive attitude clearly trying to protect the public interest and further to exercise the authority under the Bayh-Dole Act, which is difficult to do if one doesn't have the disclosure which is required under the law.

We have found a pattern at NIH, unfortunately, over the last several years that we have been working with which is quite disturbing relative to the degree with which they try to accommodate the interests of the pharmaceutical companies and act as apologists for them and refuse to engage in any kind of activities in the area of diligence that would protect the public interest on a wide range of matters.

For example, Dr. Harold Varmus is going to hold a forum on CRADA agreements on July 21st of this month in that they are going to have a series of discussions of issues including the fair pricing agreement. We specifically asked Dr. Varmus, my employer, Mr. Ralph Nader, had a discussion with Dr. Varmus and asked if we could be represented in one of the panels in one of the forums and we submitted information to the office about our interest in this matter as we have in the past on numerous occasions made requests to be more involved constructively with NIH to review the methodology for fair pricing which the Chairman knows we have been highly critical of the NIH methodologies in the past and we have taken the time to follow this and we have just asked for a place at the table, some participation.

We were told that Dr. Varmus denied our request and that only industry and Government people who were actually involved in the CRADA process would be able to participate in the panel discussions at the July 21 meeting, which dismayed us because of the lack of balance at the forum.

We were surprised when you were having your hearings on the Taxol area to have some officials of NIH to act as apologists for Bristol-Myers Squibb and make unbelievable explanations why she found it impossible to ask simple information from Bristol-Myers Squibb such as how much they had spent on producing the drug which was used in the clinical trials, which was the basis upon which Bristol-Myers was making some absurd claims as to what they ought to be able to charge for Taxol.

One of the more benign explanations for these sorts of problems is that NIH officials believe that the only important public interest involved here is the rate at which new drugs are developed. Since, in their view—in this view, I should say, the cost of drug development to consumers and taxpayers are irrelevant, they want to avoid anything that the drug industry doesn't like.

There are less benign explanations of this activity. One of the problems we have to face is the fact that a lot of NIH employees

go to work for the industry or come back and we even see cases, for example, in the case of Dr. Robert Whittis where he worked for NIH, then he went to work for Bristol-Myers Squibb working on a project that previously had been under research at NIH and was commercialized Taxol, and then he returned to the same Government agency. Or Mr. Reed Adler, last year in a hearing, Mr. Nader made some comments to the Senate Aging Committee where he said that the lawyer who negotiated the contracts for Taxol and these other drugs would be sued for malpractice if he was in the private sector. In a break at the meeting we were approached by Mr. Reed Adler, who at the time was Director of Technology Transfer at the National Institutes of Health, to express his indignation.

Today, I notice that Mr. Adler is no longer with NIH. He is with the Washington law firm of Morrison & Foerster and he also was criticizing the acts of this committee, by saying that the staff resources available to NIH for technology transfer are very limited to start with and they should be careful about how many resources are diverted to policing activities. We thought this was a fairly cynical comment given the fact that the very policing activities that he doesn't think that the NIH should bother to work with because he is concerned that they should spend most of their time on transferring property rights to the private sector, the very things that happened under his watch. He was in a position at the time to be responsible for the very problems that we are interested in right now. Particularly, since this problem with Scrips Research Institute has really been in the works for quite a while.

Now, the last area I would like to mention is in the area of remedial action. NIH has suggested that we consider to be a rather minimal activities relative to education for the grant recipients, the 1,400 grant recipients that get the 13,000 grants. We would like to suggest a different proposal.

First of all, the idea that NIH doesn't really have many opportunities to really force compliance is not already in the act. We understand the act to have considered nondisclosure of patent rights such an—such an important omission, that it actually allows the Government to take the full title of a patent. I wouldn't say taking the full title of a patent to be a very minor enforcement measure. I mean, it is the most severe penalty there can be. They are allowed to take everything.

So, the act, apparently, by providing such strong penalties should have sent a signal out to the agency that this is something that should be taken more seriously.

What we recommend is that the National Institutes of Health announce they will give a 120-day grace period to all grantees and contract recipients and ask them to review the history of their patent activity and to indicate the Government will start a random audit shortly thereafter and that 30 percent of all the patents which are identified for which disclosure was not properly made will be taken by the Government and they will impose a 2-year moratorium on future grants or contracts to institutions which were engaged in significant underreporting.

That they also, in addition to that, impose a 50 percent cut in overhead allowances allowed to the institutions for a period of 4 years. It is our opinion that if such an announcement was made,

it would be much easier to collect the information and the rate of enforcement would change dramatically. Something along that lines, that indicates and sends a signal, a shot across the bow that this is something that the Government is going to take seriously we think is in order.

I would like to also just to mention in terms of what is at stake here, there is the issue of the ability of the Government to exercise its rights, which we think are quite broad under the Bayh-Dole Act in terms of public interest positions, as the Chairman has indicated and as the Inspector General has indicated, but there also is another issue which has to do with the political effect of having the public know how much of pharmaceutical research in this country is actually developed with public funds.

There is a national debate now about whether or not to have a drug price review board and part of that debate is based on the perceptions people have about how much risks the companies bear and how much of the drug development comes from private investment as opposed to public investment. The failure to report bears on the outcome of that debate.

That is the kind of information which is needed to make an intelligent decision on that. There is another issue which comes up, that is that you are focusing on the grantee institution, and the patents that are held in the names. One of the problems that you have with the grantee institution is that the presidents of the institutions, the board members, and the professional staff have their own side deals, as you have identified in your research on the Scripps Institution last year and these types of arrangements—we have seen it at Boston University where the President of the university received hundreds of thousands of dollars in stock options. There was a series of pharmaceutical patents that were sold to the Japanese interests.

You see in the Scripps Institute where you have the president have consulting arrangements with Johnson & Johnson. They had all kinds of side deals with different scientists involving other companies. So, you have cases where it may be the institution or it may be the officers of the institution or the researchers have incentives to minimize the role of the Government so they can shield themselves from the march-in rights and other public interest responsibilities under the Bayh-Dole Act and so I think you have to take these omissions seriously. Thank you very much.

Chairman WYDEN. Thank you. You give us much to ponder and we will have some questions in a moment.

[Mr. Love's statement may be found in the appendix.]

Chairman DAVIS. Professor Davis.

TESTIMONY OF MICHAEL DAVIS, PROFESSOR, SCHOOL OF LAW, CLEVELAND STATE UNIVERSITY, CLEVELAND, OHIO

Dr. DAVIS. I have been asked to discuss several features of the Bayh-Dole Act. I am a professor of law at Cleveland State University. While all of today's issues are of interest to me, I have chosen to address only three. First, the problems and the lessons we can learn from the AZT situation, since I was co-counsel in the litigation attempting to invalidate that patent; second, the possibility that Scripps is part of a larger problem common to NIH research-

ers; and, third, whether the suggestions in the IG report are sufficient to protect the public interest.

Listening to the panel today I was reminded of a story I saw in the paper the other day about some fellow who had his car stolen. The thieves took the owner as well as the car. At the end of 100 miles they threw him out and the police came and questioned him. He said it was not so bad they stole the car, but they made him pay for the gas and the tolls.

That is what is happening to the taxpayer in this situation. Underreporting inventions developed with Government support means that the Government cannot track the compliance of a contractor who is required to market Government-supported inventions at reasonable prices under Bayh-Dole.

To the extent the Government can better track these inventions, contractors will be encouraged to comply with Bayh-Dole because the failure to comply with Bayh-Dole can trigger march-in rights by the Government allowing the licensing of such inventions to other firms.

However, march-in rights are triggered not by the procedural failure to disclose the invention, but, presupposing such disclosure, by the failure to comply with other substantive provisions of the act. On the other hand, the failure to disclose Government participation seems to trigger absolute forfeiture of the invention, a far more serious and therefore more effective penalty.

The anti-AIDS drug, AZT, was invented by Government scientists. The patenting of its use against HIV by Burroughs Wellcome and the oppressively high price it charged is notorious. Partially, however, because Burroughs Wellcome was not a small business subject to Bayh-Dole, the lessons that AZT presents for the Scripps situation are not immediately obvious. But it was the fear of congressional action, including the possibility that the Federal Government would seize the AZT patent under eminent domain theories that forced Burroughs Wellcome to lower its price.

The seizure of a patent under eminent domain theories is similar, though more Draconian I suppose, than the march-in rights afforded under Bayh-Dole. But in many ways, the economic dynamics are similar.

Thus, the AZT case is strong evidence that Scripps and other Government contractors subject to Bayh-Dole first will more readily respond to the public interest when their patent monopolies are subject to Government interventions, such as march-in, and, second, unfortunately will rationally try to minimize the reporting of inventions.

AZT is also relevant because the same alliance between the NIH and private industry which gave away that billion-dollar present to a British corporation funded by taxpayer dollars is now writing the rules and regulations that require them to surrender and abdicate the Government's responsibility for patents developed at taxpayer expense subject to Bayh-Dole.

But the larger problem of private sector compliance is equally important. Under Bayh-Dole, a contractor must report by placing the appropriate legend on a patent application that the invention was made with Government support. Compliance with Bayh-Dole is essentially self-enforcing, as we have heard today, and therefore

unreliable because any denial by an inventor of Government support with respect to an invention that was even arguably within the bounds of a Government contract would be, by definition, self-serving. All lawyers know that self-serving statements, although not inadmissible, are subject to serious scepticism.

The Inspector General has suggested increased policing by the Public Health Service and NIH which seems therefore, logical and obvious.

But the position of PHS is simply absurd because it suggests policing only those applications on which the applicant has already admitted that which is supposedly being policed. It is exactly and only those applications which do not have the legend which require further policing and exactly those upon which the PHS declines to act because they say it would involve work.

The opportunities for evading Bayh-Dole are several. The contractor or grantee must first identify the date upon which the invention was "conceived" or "reduced to practice." Those patent concepts are highly vague and uncertain and are continually litigated.

Second, a grantee must decide that a particular innovation was made in the performance of work under a funding agreement. This is similar to deciding the legal issue of respondent superior, where whether the work of an agent is that of an employee or that of an independent contractor is decided, because in both situations the scope of employment, or in this case the scope of the funding agreement, must be decided.

Thus, with so much temptation for the grantee to choose less burdensome and more potentially profitable conclusions it is highly unlikely that without close oversight Bayh-Dole will work as intended. In fact, the most simple and unsophisticated search of Patent Office records indicates a wealth of patents demanding further investigation. Last night in less than an hour working at home with a laptop, I conducted an electronic search of the patent files on the Lexus database, randomly choosing five inventors' names from the year, 1985. Taking the first five, I found 137 patents, but only 30 patents bore the legend.

One hundred seven patents by those same inventors were without the legend and of those 107, 55 were issued to those five inventors after their first Government contracts. Of those 55 patents, 36 were plainly within the area of research for which the first Government grant was made. In other words, only 30 patents contained the legend, while 36 in the same area of work as the first Government grant contained no such admission.

This is pretty much the same figure that I have been hearing from the panel this morning: Less than half. So, inventors benefiting from Government support may be identifying less than half of their inventions with the appropriate legend and I suspect also not disclosing them. Or more depressingly, you might think that Bayh-Dole is being evaded more often than it is being obeyed.

Let me go on to the third and final subject; whether Bayh-Dole and protecting the public interest in Government-supported technological innovations is adequately addressed by the IG's report.

Bayh-Dole's provisions for march-in rights are the wave of the future, I think. It is clear that a patent system premised on a completely private sector producing technological innovations is today

out-of-date. Bayh-Dole's attempt to encourage commercialization is thoughtfully balanced by the prophylactic measures such as march-in rights designed to police those institutions which fail to comply with Bayh-Dole's policies.

Those rights are justified by the fact that these patentees are enjoying a 17-year monopoly, which is unsupported by a corresponding private investment. Thus, to the extent that public funds produce technological innovations, strict compliance with Bayh-Dole is essential. To rely upon self-policing with regard to valuable properties is plainly preposterous and will produce a result which can only be called, "laissez-unfair."

I would ask if it would be too much for the Government to carefully and honestly police compliance with Bayh-Dole. Although the act contains no specific measures, the consequences for noncompliance seem sufficiently serious and potentially profitable to the Government to avoid the abuse if the act is responsibly policed.

Some of the suggestions today I think were quite good. I would suggest, for instance, that anybody could do the kind of search I did last night. Start the 60 days running and send out a form letter to each of those patentees saying that the Government is going to institute proceedings to take title and let the patentees respond. Let the burden of proof be on them and take all the work off the Government staff. If the Government were to seize a valuable patent, there is a long history of the Government sharing in royalties from licenses which it owns, including the AZT case.

There is no reason you could not justify the increased staff that royalties would bring in. The result of the failure to disclose Government participation is loss of the patented invention, of course. The cost of hiring staff to police this appears to be far less than the potential royalties that the forfeited inventions would fetch.

If I read the IG report correctly, I think they have misread Bayh-Dole when on footnote 5 it says that loss of title is an intermediate sanction. They are comparing that to march-in rights. This is backwards. Loss of title is not an intermediate sanction, it is the ultimate sanction. Something is wrong with the IG report.

Second, I must add that NIH and DER have both misread Bayh-Dole and they have abandoned and abdicated the public interest in failing to seize titles to inventions that grantees have concealed from the Government. Because the Government calls it punitive and contrary to Bayh-Dole's goal of allowing title to remain in grantees. This looks like sort of failing to enforce the shoplifting laws and letting the shoplifters keep the merchandise because the goal and the intent of the uniform commercial code is to allow consumers to take title to possessions. It is quite silly.

In conclusion, I think that with what I have heard today, we are being taken for a ride. It is no vacation and someone is asking us to pay for the gas. Thank you.

[Dr. Davis' statement may be found in the appendix.]

Chairman WYDEN. Professor Davis, you have been very helpful, and both of you have given excellent testimony. I think you also put this in the context of the real-world. I am going to start with you, Mr. Love, and in that regard. You listen to a discussion about patents and reporting and the like, and this is about as dry as it gets. This doesn't qualify for great scintillating congressional de-

bate. What really troubles me are the implications, particularly the kind of thing you looked at in pharmaceutical prices when a lot of these products get to market with taxpayer-funded research.

I was director of the Gray Panthers at home for a lot of years before I was elected to Congress, and I still stay very active in those kinds of issues. I know a lot of senior citizens, for example, who pay more than $1,000 a year out of pocket for their prescription medicine. Medicare doesn't cover prescription medicine.

It seems that a lot of the breakthrough drugs, such as the cancer drugs that are important to seniors, get to market largely through taxpayer funding. Yet, what you have found is that drugs developed with Government funding instead of being lower for the consumer, seem, in fact, to be higher than drugs developed with private funding.

In effect, I think what you are saying is senior citizens and other consumers get shellacked twice. They get hit once when their tax dollars go into the development of some of this research, and then they get clobbered again when they go to see their pharmacy or local health maintenance organization and have to pay out of pocket for prescriptions that Medicare doesn't cover.

I would be interested, if you could elaborate a little bit on this research that you have done indicating that the prices for new drugs developed with taxpayer assistance were, in fact, higher. To the extent that you can detail some of the differences between what you found with Government-financed drugs and private sector-financed drugs, I think that would be very helpful. Please proceed, if you would.

Mr. LOVE. Well, in this particular study we looked at all the new molecular entities which were approved by the Food and Drug Administration between 1987 and 1991, of which there were 117—actually, this is kind of interesting because most people I don't think realize how few new drugs really come to the market every year that are important.

During that period, the FDA issued 2,270 drug approvals, but only 117 were classified as new molecular entities which is a name given to drugs that are distinctly different in composition from drugs that are already on the market as opposed to generics or combinations of existing drugs. Of these 117 drugs, only 30 were judged by the Food and Drug Administration to be drugs that were used in the treatment of severe illnesses or to represent a substantial gain in therapeutic value. In other words, the remainder of the drugs were drugs that were roughly equivalent to other therapies that were also on the market.

This was a class that we wanted to study, the so-called breakthrough drugs and important new therapies. In fact, these are precisely the drugs that everyone wants public policy to promote the new development of.

Within that group of 30 drugs, half of them benefited for the group as a whole, half of them benefited from significant Federal funding in the development. This included funding of everything—in different drugs, everything from the preclinical research all the way up to the phase 3 clinical human use trials, although circumstances were different for each drug.

We compared the median price for the—of the 15 drugs which benefited from Government funding, to the median price of the group, the other 15 drugs that didn't benefit, and we found that the median price for the Government-funded drugs for a completed treatment was a high number, $4,854 as compared to $1,626 for the other group, which was a difference of about three to one.

Chairman WYDEN. You are saying in this list of drugs that you looked at, there was a 300 percent or 3 to 1 differential that you describe for the prices of drugs paid for with public dollars as opposed to ones where folks in the private sector just went out and went after it themselves?

Mr. LOVE. That is correct. Now, people asked us—I mean the data are what the data are. We didn't have much to say about that. But people asked us why they thought the drugs developed with Government funding were more expensive and in reviewing the data, our conclusion is that one of the major reasons is that the Government tends to focus its funding on drugs which are truly innovative and which are used to treat severe illnesses. For example, as you know——

Chairman WYDEN. That could explain some of the differential.

Mr. LOVE. Well, it doesn't explain the difference in cost; what it explains is the difference in how much people are willing to pay for it.

Chairman WYDEN. I see.

Mr. LOVE. In other words, our conclusion is that the pricing does not reflect the company's cost, but the pricing reflects the willingness of consumers to pay. If you have a child who has cancer, your willingness to pay for that drug is quite a bit higher than it would be for a drug that maybe eased some back pain or something.

Chairman WYDEN. Let me ask you about that point, is it correct to say that the majority of cancer drugs that have gotten to market in the last 20 years have gotten to market largely with taxpayer assistance? Do you have any figures on that?

Mr. LOVE. Yes, from 1955, until 1992, if you look at that time period, which was 1955 is when the National Cancer Institute began its program of screening possible treatments for cancer, there were 37 drugs approved by the Food and Drug Administration for the treatment of cancer. Of the 37, 34 benefited from extensive public support. Of the 34 drugs the Government contributed—provided for the financial support and development, all of them benefited from Government funding of the human use clinical trials, and about half the cases, the Government was directly responsible for the invention of the drug, either because it funded the—either because the discovery occurred in a Government lab or it gave a grant to an agency which discovered the drug in the preclinical phase. So, the Government's involvement was extensive in both the preclinical and the clinical phases.

Chairman WYDEN. I gather that you think that it has been difficult to get information on other important matters besides patents; is that correct? And if so, what kind of information are you talking about?

Mr. LOVE. First, I would like to say that with respect to patents, we have long since learned to not rely upon the information in the patents because, as the other witnesses here have reported, we

have also found that patents are unreliable sources of information about whether the Government had a role. One of the reasons for that is because in some drugs, such as levamisole, it might be the case that the important research takes place after the patent is issued in terms of the real breakthroughs that occurred at the Mayo Clinic on that drug, for example.

In other cases, such as in AZT, the company was incredibly circumspect about what it believed the Government's role to be, and tended to overemphasize its own achievements. In other cases, as you see in the Scripps case, it is just a failure to report. Mr. Michael Ward here spends a lot of his time tracking these things down, but it is so time-consuming, we are even reluctant to regularly update the search results because it requires such a massive investment of our time in trying to trace back the history.

We have recommended here that this would be solved if the Food and Drug Administration requires as a matter of course that for every drug that is approved that there be a complete history of any Government involvement in the funding of the drug, whether or not a patent is involved. I mean, as there are a lot of important drugs protected by the Orphan Drug Act as you know, which are priced in some cases several hundred thousand dollars for a year of treatment, in many cases involving thousands of dollars, where no patent exists.

If I could comment on your Gray Panther experience, I would like to recount one brief experience involving levamisole which I think is relevant, as you mentioned the issue of the thousand dollars. The cost of levamisole to a consumer over a year is over $1,000 for a lot of patients; over $100 a month. We raised the pricing issues about levamisole.

It is priced 100 times more for people than it is for sheep and there is this controversy over it. We were told by Dr. Bruce Chandler that levamisole was no big deal because it was so cheap. It was a bargain. It was less expensive than all the other cancer drugs and he thought it really shouldn't concern us. It wasn't important.

I think that is the perspective of someone that has a very good salary and benefits package from the Federal Government and maybe has a medical degree, but I don't think it is a perspective of an elderly person who has colon cancer and, as you pointed out, has no insurance coverage for the drug and for which that represents a fairly significant amount of money.

Chairman WYDEN. Let me ask you one other question. It seems to me that as you listen to what has been discussed today and we have been at it, I guess, 3 hours or something like that, that the problem has been these kinds of issues that give the Government and the taxpayers leverage with respect to prices, and leverage with respect to the small business community, and the kinds of things we have been examining today have essentially been an afterthought over at the National Institutes of Health.

My sense is what is really going to be needed—and you have offered ideas, my friends Mr. Combest, Mr. Skelton and others have looked at ideas, is that it will be essential to the National Institutes of Health to make a cultural change where they say that this kind of information is a priority. This kind of information is what

taxpayers are entitled to, that to protect taxpayers' interests, they have got to be able to get it and they have got to be able to get it as the law stipulates promptly. I am wondering what your reaction would be to that?

Mr. LOVE. I think from our point of view, we are rapidly losing confidence that NIH is committed to this. We thought we saw some movement toward a more public interest position during the Bush administration. It was modest and it was far inadequate from our point of view, but we thought that when the Clinton administration came in it seemed to make the pricing of drugs a big national issue. We thought that we could expect much more on behalf of the Clinton administration.

We have seen some retrenchment from NIH. I think the most disturbing thing to us is that the reasonable pricing clause in the NIH licensing CRADA agreements, which was really by itself a minimal requirement, we think that the NIH is thinking about walking away from that. If you look at agenda and the draft mandate that Dr. Varmus issued as far as the July 21 meetings he is having, he is asking the industry to comment on—the question is: Given the mandates of NIH to support research and transfer, the results of that research to advance the public health, should the reasonably pricing clause be used by NIH as a mechanism to reflect the public investment in NIH-supported research brought to market through NIH private sector collaborations?

Well, he asking this to a panel that includes only industry and Government officials. I can predict right now the answer he is going to get to that question. If he acts on that, if he uses that as any kind of a basis—what you have got here is an agency that shuts out and refuses to deal with the people who have been critical of the industry and wraps its arms around the major pharmaceutical companies.

Chairman WYDEN. Let me move on to Mr. Davis. I want to recognize our friends on the minority for any questions that they might have.

Dr. Davis, what you seem to be saying, and it is really striking, that here we are after hours of listening to the National Institutes of Health and others talking about how the system is complicated and paperwork and all of this kind of thing, is that after you were sitting there at your computer for a couple of hours last night, grantees and companies almost have to go out of their way to not include the Government funding clause in their patent paperwork. In your view, this is really quite simple.

It is not the kind of thing that people ought to miss constantly, as we have seen. It is not the kind of thing that you ought to just inadvertently muff all the time. They almost have to work at it to avoid putting this kind of information out. Is that what you come to tell us?

Dr. DAVIS. Yes, I think that is a nice way to put it, actually. I have tenure, so I usually can put it much more directly. I smell larceny in the air. If I were to search out patents that were concealing Government support, I would go further than what the Inspector General did. They did a good job, obviously, but I would not search grantees. I would search inventors. Under the patent statute, the

only person who has to be identified is the inventor. It is the inventor's name that you search for.

Once you find the inventor's name, you just keep following the trail and you will be astonished at the number of inventions that pop up in the same exact field. There was one inventor last night getting a grant on vitamin D in 1985, and there were 77 more patents all on vitamin D. I am not an expert on vitamin D, but it is pretty difficult to imagine that Government funding didn't contribute to a whole lot or to even all of his research on vitamin D, but only half of those inventions had the legend that they were developed with Government support.

Chairman WYDEN. Well, we will ask the folks at NIH and across the governmental landscape about the vitamin D matter. I just keep coming back to the same idea. Even if you are sitting there with your computer and you can pull up this stuff in the matter of hours, and the Inspector General tells us essentially the same thing, I find it hard to fathom this NIH point of view that somehow it is beyond the realm of their talents. You have been very helpful to us. I gather that you would think that this idea of hooking NIH up electronically with the patent office, as well, would be something that would be straightforward and relatively easy to do.

Dr. DAVIS. Oh, yes, I think that would be the first step. I think Scripps' suggestion that somehow it is sort of like people on probation, all they wanted was to have workshops on how to be honest is certainly below what the situation demands. I would not be so proud as to call myself the crown jewel of research. The crown jewels are usually obtained by looting the public. So, I would be a little careful. I think it is time to call the cops.

Chairman WYDEN. Let me recognize our friends from the minority for any questions they would care to ask.

MINORITY COUNSEL. No thank you, Mr. Chairman.

Chairman WYDEN. All right. Gentlemen, you all have been very helpful. Obviously, there is much to do here; $8 billion is at stake. We're talking about cures for dread diseases and we're talking about financial opportunities and jobs for small businesses. We thank you for your patience and we're going to stay with this until we turn the system around.

The subcommittee is adjourned.

[Whereupon, at 12:30 p.m., the subcommittee was adjourned, subject to the call of the chair.]

APPENDIX

LARRY COMBEST
19TH DISTRICT, TEXAS

COMMITTEE ON AGRICULTURE
COMMITTEE ON SMALL BUSINESS
PERMANENT SELECT COMMITTEE ON INTELLIGENCE

ROOM 1511
LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-4319
(202) 225-4005

Congress of the United States
House of Representatives

DISTRICT OFFICES

ROOM 613
FEDERAL BUILDING
LUBBOCK, TX 79401
(806) 763-1611

SUITE 205
3800 E 42ND STREET
ODESSA, TX 79762
(915) 362-2631

SUITE 205
5809 S. WESTERN
AMARILLO, TX 79110
(806) 353-3945

SUITE 114
511 W. OHIO
MIDLAND, TX 79701
(915) 687-0926

OPENING STATEMENT OFTHE HONORABLE LARRY COMBEST
19TH DISTRICT OF TEXAS
HOUSE SMALL BUSINESS SUBCOMMITTEE
ON REGULATION, BUSINESSES OPPORTUNITIES, AND TECHNOLOGY

JULY 11, 1994

Mr. Chairman, I would like to thank you for holding this hearing and for your opening remarks.

Today's hearing is another in the series that has examined the Scripps Research Institute's compliance with provisions of the Bayh-Dole Act. As I understand, also at question today, is compliance of the National Institutes of Health with its responsibilities under Bayh-Dole.

In this case we already know the "juicy" parts of the story. Both Scripps and NIH have been found to be remiss in their respective responsibilities under Bayh-Dole. Each have acknowledged their failings.

I would like to underscore my concern that although Scripps is held up for examination today, we should not be surprised to learn that other institutions also may have not done a good job with their bookkeepping. I would like to gain a better sense of the extent of this disclosure failure, and perhaps when NIH has straightened-out its own records, we can find out.

I see only two principal questions remaining: One, what will NIH and Scripps each do to come into compliance with the Bayh-Dole Act? And two, how can we be sure that our Federally-sponsored researchers will act in the public interest? Hopefully the witnesses assembled here today are prepared to speak to these concerns.

On many occasions this Subcommittee has heard excellent testimony celebrating the successes of the Bayh-Dole Act. Those successes are something agreed to by the Federal funding agencies, academic research institutions, and industry. Where we have observed shortcomings in Bayh-Dole, I look forward to working with Chairman Wyden, and the experts, to provide a clearer and more effective law. I would, of course, wish to seek a sensible balance between full accountability to the taxpayers and unfettered business opportunities.

We do have a big responsibility that I do not wish to minimize. The history of cooperation between academic research institutions, Federal funding agencies, and corporations have been, and continue to be quite successful. The results are seen in good paying jobs in the private sector; enhanced competitiveness in an international economy; and most importantly new treatments and cures for the American people.

OPENING STATEMENT
REP. RON WYDEN

BEFORE THE SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES AND TECHNOLOGY

THE NIH HAS FAILED TO PROTECT VALUABLE PUBLIC INTERESTS
IN FEDERALLY FINANCED MEDICAL TECHNOLOGIES

July 11, 1994

Today, the Subcommittee on Regulation, Business Opportunities and Technology continues its inquiry into the protection of vital public rights in biomedical technologies developed through federal grants.

Specifically, the subcommittee will examine flaws in procedures at the National Institutes of Health for monitoring and protecting a variety of public rights to federally funded scientific innovations which lead to a plethora of new drugs and medical devices.

This is a matter of great importance to taxpayers for several reasons. The government is now paying almost $8 billion per year through the NIH and to a lesser degree the National Science Foundation to fund research on medical breakthroughs at scores of colleges, universities and medical institutions around the country.

As a result of this massive federal investment, the federal government has certain rights and interests including an assurance of reasonable pricing and availability of products commercialized as a result of this research. In addition, the taxpayers have an interest in ensuring that these technologies are developed and manufactured in a way that creates family-wage jobs in our country. Specifically, the government can use its leverage to force co-licensing of technologies, and competing drugs and devices, or even, in the case of flagrant disregard of the public interest, it can take ownership of the patent.

Today, the subcommittee examines an audit done at our request by the inspector general of the Department of Health and Human Services which states: "Fundamental problems exist with NIH's ability to monitor" those scores of institutions who benefit from these billions of dollars per year in federal research largess. Further, the auditors found that the NIH "lacks information to ensure compliance with the law and regulations."

Unfortunately, the current system often fails to record taxpayer interests in these technologies, and safeguard important public rights.

The IG used Scripps as its case study. Initially, some 18 months ago, NIH records indicated to the IG that only 5 of 125 patents issuing to Scripps over the last decade had some federal grant involvement.

When the IG contacted Scripps, the Institute initially admitted to 51 patents with federal government support.

More than a year later, and after prodding from the IG, Scripps admitted to 94 patents that had had federal funding.

The central problem, says the IG, is that institutions are functioning according to an honor code. Whether grantees chose to reveal the government's involvement or not appears to be entirely discretionary. The NIH enforcement system seems toothless.

In effect, NIH seems dependent on a failed policy of "Don't Ask. Don't tell. Don't pursue."

At a minimum, an $8 billion research program is too large to operate with the federal government allowing private interests to say "trust us."

The Chair believes it is highly unlikely that these institutions will plug the meter if there is no parking enforcement by the NIH.

This is not just a theoretical issue.

One successful example of protecting taxpayers' interests was the government's handling of AZT...the AIDS drug.

Burroughs-Welcome had priced this government-financed drug sky-high...well out of the reach of many patients.

Using the provisions enacted by Congress for the purpose of commercializing government-supported technologies, the government said it would sue Burroughs to force co-licensing the drug. This would have created competing AZT products, and potentially lower prices for the consumer.

Because the government used its leverage to protect the public, Burroughs sliced its price in half....not once, but twice.

But again, the key was that taxpayer involvement in funding the underlying research was carefully described in the AZT patent.

The Chair believes that Scripps is a microcosm of a much larger problem afflicting the entire NIH extramural research community. Although outside the scope of its Scripps audit, the inspector general has disclosed to us that a rudimentary analysis of patent activity at several other large, federally financed research institutions around the country indicates similar, disproportionately low levels of federal support ascribed to technologies underlying patents issuing to these institutions.

To quote from Ms. Brown's June 15, letter to Assistant Secretary of Health Philip Lee: "We believe additional audit work is warranted to determine the full extent of this problem."

The response of the NIH to this troubling report unfortunately is underwhelming. For example, the IG has recommended that the agency should develop a procedure which will allow it to obtain information directly from the U.S. Patent Office with regard to patents issued to all NIH grantees. And with that information, the NIH Division of Extramural Invention Reports should determine whether patented inventions were supported by NIH funds.

Instead of better protecting the public interest, the NIH wants to continue business as usual, sticking with a system that is overly reliant on grantees voluntarily doing the right thing. They seem to argue that watchdogging taxpayer rights to these technologies will be "an enormous burden."

The subcommittee would like to know what burden is posed by a computerized system that will file the reports establishing the taxpayers' interest electronically, and with the assistance of the Patent Office?

The NIH should perform its job on tracking and auditing, or in the alternative hire an outside contractor for that duty. This is an idea that my colleague Larry Combest is examining. I think it might be an entirely appropriate fix if NIH either can't perform, or refuses to perform, this valuable mission. No doubt, this would be a good opportunity for small businesses already involved in auditing of this type on a consultive basis.

Another answer is to hand over this enforcement task to the Department of Commerce, which has some oversight responsibility in this area. If the NIH makes the case, today, that it's a Commerce job then I will request that within a time certain these two agencies draft and sign a memorandum of agreement that describes exactly what each one will do separately, and together, to solve these problems.

The public deserves better than the status quo. The taxpayer deserves a better system than the one proposed by the NIH and the Public Health Service.

We thank our witnesses for their cooperation, and we welcome them to today's hearing.

Testimony of
Michael R. Hill
Assistant Inspector General for Public Health Service Audit Division
Office of Inspector General
Department of Health and Human Services

NIH Oversight of Extramural Research Inventions and The Scripps Research Institute Experience

Good morning Mr. Chairman and members of the Subcommittee. I am Michael R. Hill, Assistant Inspector General for Public Health Service Audits, with the Office of Inspector General at the Department of Health and Human Services. Our statutory mission is to promote economy, efficiency, effectiveness, and integrity in all Department of Health and Human Services programs. One method by which we accomplish our mission is focusing on systemic problems; we target areas of high vulnerability and concentrate on ensuring that program weaknesses are corrected. I am pleased to be here to share with you the observations, findings, and recommendations from two Office of Inspector General (OIG) reports which detail one such systemic problem at the National Institutes of Health. The first report, which this Subcommittee requested, is our audit of the Scripps Research Institute (SRI). The second report is an inspection of the National Institutes of Health (NIH) ability to monitor grantees' compliance with the law and regulation dealing with invention reporting. The inspection was underway at the time you requested the audit of SRI and was unrelated to your request.

BACKGROUND

As the nation's premier biomedical research institution, NIH accomplishes its mission, in part, through funding research at grantee institutions such as universities, medical schools, hospitals, and research organizations. In 1993, NIH awarded more than $7 billion in grants to support biomedical research at these grantee institutions.

Because of the nature of biomedical research, it is not uncommon for NIH grantees to discover technological breakthroughs and develop new patentable technologies. Critical issues dealing with grantee invention reporting and ownership of inventions resulting from Federally funded research are addressed in the Patent and Trademark Amendments Act of 1980--more commonly known as the Bayh-Dole Act. The Act allows grantees to acquire title to inventions and file for a patent application for technologies developed with Federal research funds. Grantees then can earn royalty income by providing industry with exclusive or nonexclusive licenses to patented inventions.

With such a large investment of public funds in research, it is important to ensure that the objectives of the Bayh-Dole Act and interests of the American taxpayers are protected. Two of the seven objectives of the Act deal with providing preference for United States industry and labor and ensuring that the Government obtains sufficient rights in inventions to protect the public against nonuse or unreasonable use of inventions. To assist the Government in monitoring these objectives, implementing Federal regulations require the grantees to provide the

granting agency with reports disclosing the inventions and reports showing how inventions are used.

Our work, however, indicates that fundamental problems exist with NIH's ability to monitor grantees' compliance with the regulations. NIH does not have a system of coordinating data with the United States Patent and Trademark Office (USPTO), or other sources of information, to ensure NIH is receiving accurate and complete reports from grantees. Further, NIH does not perform reasonability checks or otherwise analyze data it receives from grantees to help determine if the objectives of the Act are being met.

To understand the context of these findings, let me briefly review the Federal legislation governing patent rights to grantee inventions.

THE BAYH-DOLE ACT

Prior to 1980, there was no uniform Federal policy for dealing with inventions developed through extramural research. Congress enacted the Bayh-Dole Act (the Act) in 1980. The principal purpose of the Act was to foster development of inventions produced with Federal research funding, particularly by small businesses and non-profit organizations. In 1984, the Trademark Clarification Act amended the Bayh-Dole Act, providing even greater flexibility to certain grantees in licensing inventions and assigning responsibility for developing regulations to Department of Commerce. The Commerce regulations are applicable to all Federal agencies.

The regulations include a standard patent clause (Government Rights Clause) that is to be incorporated in all funding agreements. The clause outlines the rights and responsibilities of Federal agencies and grantees regarding subject inventions. When a grantee develops an invention supported with NIH grant funds, the Act and subsequent regulations require grantees to disclose the invention to NIH within 60 days. The regulations require disclosures to be in the form of a written report and sufficiently complete in detail to convey a clear understanding of the invention.

The regulations further require the grantee to elect to retain title to the invention within two years of disclosing the invention to the granting agency. A patent application with the United States Patent and Trademark Office (USPTO) must be filed within one year after retaining title. If a patent application is filed, a grantee is also obligated to include a statement in the application that the invention was made with Government support.

The grantee must also provide the Government with a nonexclusive, nontransferable, irrevocable, paid up license to use the invention. According to NIH, the nonexclusive license also allows the Government to obtain the technology or product without paying a royalty, which is normally included in the purchase price of drugs, devices, and other products produced using the new technology.

When the original grantee has not taken (or is not expected to take) effective steps within a reasonable time to achieve practical application of an invention, or when it is necessary to alleviate health or safety needs, the Government can assert what is termed "march in" rights.

to list, for the top 25, the number of patents containing the Government rights clause. We found that the 25 universities received 4,935 patents, however, only 1,818 or 37 percent contained the clause--SRI originally showed that only 41 percent of its patents were Federally supported, after we completed our audit, SRI indicated that 75 percent were Federally supported. We provided NIH with a copy of this list and requested that NIH ask these universities to review their patents and determine if they may also have underreported the Federal involvement in the development of the patented invention.

NIH OVERSIGHT OF EXTRAMURAL RESEARCH

Earlier this year, we issued a final inspection report on NIH's monitoring of grantees' compliance with the requirements of the Bayh-Dole Act. We found that NIH has limited its oversight of grantees and lacks a systematic process for ensuring that grantees submit required invention information. Our inspection also found that NIH did not fully utilize its invention data base to monitor grantees. We recommended that NIH re-examine its oversight role, add more detailed information to its data base, and use it to track grantee compliance.

NIH ADMINISTRATION OF THE BAYH-DOLE ACT

The NIH Division of Extramural Invention Reports (DEIR) is responsible for overseeing grantee compliance with Federal regulations concerning invention reporting. Since 1991, DEIR has been under the direction of the Office of Policy for Extramural Research Administration (OPERA).

NIH has primary role in ensuring grantee compliance with Federal regulations

While NIH and the Department of Commerce are both granted certain areas of review by the regulations promulgated by Commerce, both agree that NIH has the primary responsibility for tracking its grantees' compliance with the regulations. Although NIH has primary oversight responsibility, NIH applies the regulations designed by Commerce. Therefore, NIH has on occasion requested clarification from Commerce when determining what would constitute compliance with certain parts of the regulations. It is important to note that the Department of Commerce views itself as an ombudsman for complaints concerning compliance with the regulations. If a complaint were received, it would be sent to the appropriate agency for review with a request that the agency share the results with Commerce.

According to Commerce, the regulations allow for decentralized agency decisions on how to implement policies. Commerce relies on individual agencies to implement their policies within the broad legal parameter of the regulations. Commerce recognizes that agencies differ in their level of oversight and has no official opinion on what the appropriate level should be.

There are two areas where NIH and Commerce share responsibility for oversight: exceptional circumstances and ensuring that nonprofit grantees give preference to small businesses when making licensing decisions.

Exceptional circumstances occur when NIH determines that restriction or elimination of the grantee's right to retain title would better achieve the Bayh-Dole objectives. When NIH determines that exceptional circumstances exist, it is required to prepare a written analysis justifying its decision. It shares this analysis with the grantee and the Secretary of Commerce, who reviews NIH's determination. If NIH's determination is found not to conform with the policies and objectives of the regulations, Commerce may recommend corrective action.

While both agencies agree that Commerce would handle complaints, neither actively monitors grantee compliance with the small business preference requirement. Under the regulation, nonprofit grantees are required to make reasonable efforts to attract small business licensees. Grantees must also give preference to small businesses when their marketing plans are as likely to bring about commercialization as the plans of larger businesses. While NIH indicated that problems would be forwarded to Commerce for review, we did not find a formal mechanism by which NIH would either identify problems or share information with Commerce.

Both NIH and Commerce agree that the granting agency is responsible for making grantees aware of their rights and obligations under Bayh-Dole. The NIH believes it fulfills this responsibility by providing several documents to grantees. All Public Health Service (PHS) grantees receive the PHS Grants Policy Statement, a resource manual. Unlike the National Science Foundation which places the standard patent rights clause in its manual, the PHS manual provides only the citation for the pertinent Commerce regulations under the Patent and Invention section. It also explains the different invention reporting requirements. New grantees receive a "welcome wagon" letter advising them of their responsibilities. The Institutional Patent Policy Section of this letter cites the Commerce regulations and advises grantees to refer questions to the appropriate NIH extramural inventions office. The letter also states, "It is expected that institutions will rely primarily on their own legal counsel for advice and interpretation of relevant laws and regulations."

Several notices explaining invention reporting requirements have been published in the NIH Guide for Grants and Contracts, a weekly publication sent to all grantees and interested parties. To make grantees aware of their obligations, invention and patent requirement information has been published in the Guide five times since February 1990. Information about patent requirements also appear in the Application for Public Health Service grants and in the application for contracts and Small Business Innovation Research.

NIH oversight of grantees is limited

The NIH requires documentation only for certain requirements, thereby limiting its oversight role. Some of this documentation is required by regulation, some is allowed but not required, and some is not mentioned in the regulation at all. The NIH requires grantees to submit documentation for invention disclosures, elections of title, utilization reports, patent applications, issued patents, and the U.S. non-exclusive licenses. The NIH does not require grantees to submit licensing agreements, certification of meeting royalty requirements, or certification of efforts to give licensing preference to U.S. industry and small businesses. While the regulations outline these requirements, they are silent on how the requirements should be documented. Since NIH does not require documentation of these requirements, it is unable to determine the extent of grantee compliance.

Our inspection report contains a more complete discussion of these reporting requirements. However, I should point out a few significant findings:

U.S. Industry and Small Business Preference

Since NIH neither reviews the licensing process nor obtains a copy of the invention license, it is unable to determine whether grantees are complying with the U.S. industry and small business preference requirements. When a grantee licenses an invention, it allows a firm to use the invention to commercialize the product in exchange for a licensing or royalty fee. Regulations require that all grantees license to companies that will manufacture the invention substantially in the U.S. and that nonprofit grantees give preference to small business.

In the case of the U.S. manufacturing requirement, grantees may apply for a waiver if reasonable efforts to meet it are unsuccessful. With no formal documentation required, the only way NIH learns this requirement is not being met is when a grantee requests a waiver or if a complaint is received. Last year, NIH surveyed approximately 100 universities to review their invention information and research-support agreements. The survey found that only 20 percent of the research-support agreements had clearly established U.S. manufacturing clauses.

The NIH has no formal mechanism to determine whether nonprofit grantees have given preference to small business. According to their survey, approximately 44 percent of research-support agreements collected were with small businesses.

Sharing Royalty Requirements

The NIH does not require any certification, financial reports, or other information from nonprofit grantees to verify compliance with the royalty requirements in the Federal regulations. The NIH considers this proprietary information. They also consider the royalty requirements to be self-enforcing, believing that inventors would advise NIH if grantees failed to comply.

According to Federal regulations, any royalties received from the licensing of inventions must be shared with inventors. In addition, the balance of royalties after expenses must be used to support scientific research and education. The Federal regulations do not specify what information granting agencies need to collect to verify that royalty requirements are being met.

NIH lacks a systematic process for ensuring grantees submit required information

The NIH does not follow up systematically with grantees to ensure that all required invention information is submitted. Although NIH does require grantees at the end of a grant to certify if any invention occurred during the granting period, NIH has no way of knowing if grantees are providing accurate information. Without this information, NIH may not be aware of inventions funded with their research dollars and can not be certain that grantees are complying with Federal requirements. Moreover, while NIH requires grantees to submit required documentation within specific time frames, it has not created a system for determining whether documents are submitted timely.

Due to a lack of staff time and resources, the DEIR has not made reviewing grantees for timeliness a priority. The Division has stated that it instead focuses on ensuring that Government rights are recognized through the acknowledgement of Government support in the patent and through the granting of the Government's non-exclusive license. According to NIH, they do not perform strict monitoring of grantees believing that grantees are responsible for ensuring that the terms of their funding agreements are met. The NIH explained that it is in the best interest of the grantees to comply because the title to inventions is at stake.

The DEIR has chosen not to penalize grantees who do not send information when required. While the regulations allow granting agencies to take title to grantees' inventions if they do not meet certain requirements, NIH believes this punitive approach is contrary to the primary Bayh-Dole objective of allowing grantees to retain the rights to their inventions. Instead, when problems arise, DEIR informs grantees of their requirements and asks that the necessary information be sent.

NIH invention database is not fully utilized

The NIH is not fully utilizing its database's potential for monitoring or reporting out information. Information from the database could be used periodically to inform grantees that certain requirements have not yet been met. More complete information on commercialization could be recorded in the database and then reported to NIH management and the public. This outcome information would illustrate one benefit of public research funding.

While DEIR is aware of its database capabilities, large workloads and few resources do not allow them to fully use the database. A limited DEIR review of the invention and licensing information sent by approximately 30 universities recently surveyed found that in more than half of the cases the information sent by the universities did not match the information in DEIR's files. Improving the monitoring capabilities of the database could improve grantee compliance with requirements.

RECOMMENDATIONS

We offered several recommendations to address the specific problems of underreporting we found in the case of SRI and the fundamental problems we identified with NIH's oversight of extramural research inventions.

NIH action is needed to address underreporting by SRI

With respect to SRI, we recommended that PHS have NIH examine the remaining patents SRI claims were not developed with the help of Federal funds and determine if SRI's assessment of the Government's involvement is correct. PHS concurred with this recommendation. We have been informed by the agency that it is reviewing 35 patents that SRI stated were not funded with Government support. According to NIH, preliminary results show that 11 of the 35 were

developed with Government support. The NIH expects to complete its review of these patents and issue an opinion regarding Government involvement by December 31, 1994.

We also recommended that PHS have NIH determine the extent of noncompliance by other grantees with reporting requirements found in the Act, and NIH Guidelines. On this recommendation, PHS informed us that it concurred with the intent of our recommendation and stated it has taken steps to enhance its oversight capabilities for ensuring grantees compliance with reporting requirements. The PHS informed us that NIH is developing a new system to track inventions reported to it by grantees and stated it intends to coordinate information on technology transfer now maintained by the Association of University Technology Managers (AUTM).

We do not believe, however, that NIH's actions will allow it to fully determine compliance with reporting requirements. The PHS did not state how NIH will use the AUTM data to determine the extent of grantee noncompliance with current reporting requirements. Our understanding is that AUTM's data on inventions, patents and licenses is obtained on a voluntary basis from universities and others. If a grantee does not disclose an invention or patent to PHS or to AUTM, NIH will have no way of determining grantee compliance with reporting requirements of the Act. An SRI official, for example, informed us that SRI does not report information on its patents to AUTM.

We believe NIH should maintain information on patents awarded by the USPTO. The NIH could investigate those grantees which, based on a review of the data from the USPTO, appear to be underreporting inventions to NIH. For example, NIH might review the USPTO patents of selected grantees and investigate those that show an unreasonably low percentage of their patents were developed with Government funds.

Our final recommendation concerned the development of procedures to obtain, from the USPTO, information on patents issued to NIH grantees and that the Division of Extramural Invention Reports should determine whether such patented inventions were supported by NIH funds. The PHS indicated that it concurred with our recommendation if the intent of the recommendation was for NIH to validate USPTO data to NIH files when the Government rights clause is included on the patent. The PHS stated it does not agree with our recommendation if the intent is to require NIH to validate USPTO data against NIH data for all grantee patents not indicating Government support. The PHS claims that the latter would require too much work.

We disagree with PHS. If NIH only validates USPTO data when the Government clause is included in the patent, it will not detect underreporting similar to that which existed at SRI. Our recommendation is intended to suggest an approach that would allow NIH to identify those cases where inventions should have been, but were not, reported and where the rights clause should have been, but was not, included in the patent. With respect to NIH's position that our recommendation would require too much work, we suggest that NIH might use a risk-based approach that would ensure that those grantees most likely to have inventions and file for patents are reviewed. We continue to have problems with NIH's procedures for assuring that its grantees are in compliance with reporting requirements.

NIH should improve monitoring of grantee compliance with Bayh-Dole requirements

With respect to the findings in our inspection report of NIH's monitoring of grantees, we recommended that NIH reexamine its current oversight role to determine what improvements could be made in the monitoring of grantee compliance with Bayh-Dole requirements. While we believe the NIH monitoring role should not be so constricting as to hinder the overriding purpose of commercialization that is central to the intent of the Bayh-Dole Act, we also believe that NIH needs to have an effective monitoring role to preserve the additional Bayh-Dole Act objectives of protecting the public investment in research and promoting small businesses and U.S. manufacturing.

We believe the NIH needs to increase its monitoring of grantee compliance especially in the areas of royalties, and small business and U.S. manufacturing preferences. In responding to this recommendation, NIH indicated it had made a major step in evaluating its current oversight role of Bayh-Dole through the sponsoring of a two-day public forum by the Task Force on the Commercialization of Intellectual Property Rights from Extramural Research. However, while we agree with the finding of the forum that NIH monitoring should not overburden research institutions to the point of hindering the goal of technology transfer and commercialization, we are not convinced that self-monitoring by grantee institutions will ensure that the objectives of Bayh-Dole will be met. We continue to believe that NIH must exercise a strong monitoring role in order to ensure that an equitable balance is struck between commercializing federally-supported inventions and protecting the public's investment in research.

Finally, to create more effective monitoring procedures, the NIH may wish to determine whether it needs to recommend that the Department of Health and Human Services issue its own regulations for implementing Bayh-Dole requirements. Issuing such regulations may clarify NIH and grantee responsibilities under the Bayh-Dole Act.

NIH should collect more detailed licensing and utilization information.

We also recommended that NIH, (1) collect more detailed licensing and utilization information, and (2) track grantees for timely compliance. The NIH concurred with this recommendation and has indicated it plans to add electronic transfer as a means of reporting.

Furthermore, we believe that NIH's management of this area could be improved if it obtained patent data from the USPTO and Dialog and maintained systems that compared and reconciled this data with information provided by SRI and other research organizations. Without such information, NIH is not in a position to determine whether the objectives of the Act are being met with regard to sponsored activities.

CONCLUSIONS

When the Government is not aware of a grantee's invention, it is not able to exercise its rights and to protect the taxpayers' interests. For instance, the Government may retain rights through a nonexclusive license to use the invention, and the right to restrict title, in exceptional circumstances, to better promote the policy and objectives of the Act. Moreover, according to NIH and DOC officials, the Government has the right to obtain the technology without paying a royalty, which is normally included in the purchase price of the product. If the Government is unaware of situations where it might obtain nonexclusive licenses, it may be missing opportunities for savings on purchases of medical supplies or devices.

Mr. Chairman, we appreciate your interest and support in examining these important program issues. As the Government's investment in Federal research dollars continues to rise, it is important that the American citizens are ensured of a fair return on their tax dollars, where such a return is warranted. Although our work has identified a weakness in NIH's oversight in this area, it is important to note that the full extent of this problem is not known.

This concludes my remarks, Mr. Chairman. Thank you for including us in this important dialogue. At this time, I will be happy to answer any questions which you and other members of the Subcommittee may have.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date JUN 15 1994

From June Gibbs Brown
Inspector General

Subject Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute (CIN: A-15-93-00029)

To Philip R. Lee, M.D.
Assistant Secretary for Health

The attached report alerts you to weaknesses in procedures at the National Institutes of Health (NIH) for monitoring compliance with provisions of the Patent and Trademark Amendments Act (Act) of 1980 at the Scripps Research Institute (SRI) of La Jolla, California. The objectives of the Act are, in part, to promote utilization of inventions and technology arising from federally supported research and development, require manufacture of patented products in the United States, protect the public against nonuse or unreasonable use of new technologies, and ensure that the United States obtain sufficient rights in inventions.

We found that NIH did not have effective procedures to detect that SRI underreported, in its patent applications, NIH's involvement in inventions resulting from NIH sponsored research. Because NIH was not aware of inventions being developed at SRI with NIH grant funds, it could not provide assurance that the objectives of the Act were being met. Information we obtained from NIH showed that only 51 (41 percent) of the 125 patents awarded to SRI were developed with help from Federal grant funds. However, after we raised questions about the accuracy of SRI's reporting, SRI, on June 30, 1993, revealed to NIH that 94 of the 125 patents were developed with the help of Federal funds.

We recommended that the Public Health Service (PHS) have NIH determine if SRI properly reported all patented inventions and that NIH establish procedures to better monitor SRI's compliance with the Act. The PHS generally concurred with our recommendations, however we continue to have concerns regarding the adequacy of NIH planned procedures for assuring that other grantees complied with the Act's reporting requirements.

We would appreciate being advised within 60 days of the status of corrective actions taken or planned on each recommendation. If you have any questions, please call me or have your staff contact Michael R. Hill, Assistant Inspector General for Public Health Service Audits, at (301)443-3582.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

UNDERREPORTING FEDERAL INVOLVEMENT IN NEW TECHNOLOGIES DEVELOPED AT THE SCRIPPS RESEARCH INSTITUTE

JUNE GIBBS BROWN
Inspector General

JUNE 1994
A-15-93-00029

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

JUN 15 1994

Memorandum

Date

From June Gibbs Brown
Inspector General

Subject Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute (CIN: A-15-93-00029)

To Philip R. Lee, M.D.
Assistant Secretary for Health

This final report alerts you to weaknesses in procedures at the National Institutes of Health (NIH) for monitoring compliance with provisions of the Patent and Trademark Amendments Act (Act)[1] at the Scripps Research Institute (SRI) in La Jolla, California. Our audit was requested by the Chairman, Subcommittee on Regulation, Business Opportunities and Technology, House Committee on Small Business.

We found that NIH did not have effective procedures to detect that SRI underreported, in its patent applications, NIH's interest in inventions resulting from NIH sponsored research. Because NIH was not aware of the patenting of new inventions which had been developed at SRI with NIH grant funds, it could not provide assurance that the objectives of the Act were being met. Such objectives include that patented products are manufactured in the United States, and that the public is protected against nonuse or unreasonable use of new technologies.

Specifically, information we obtained from the United States Patent and Trademark Office (USPTO) and a commercial data base showed that only 51 (41 percent) of the 125 patents awarded to SRI were developed with help from Federal grant funds. However, after we raised questions about the accuracy of SRI's reporting to NIH, on June 30, 1993, NIH was provided data indicating 94 of the 125 patented inventions were developed with the help of Federal funds--SRI also provided information on additional patents.

Although our review focused on SRI's reporting of Federal involvement in patent applications to the USPTO, we also found that NIH was not always aware of new inventions developed by SRI. For example, we found that NIH did not have disclosure records for 22 inventions that had already been patented by SRI. We believe additional audit work is warranted to determine the full extent of this problem.

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[1] Public Law (P.L.) 96-517, and amended by P.L. 98-620 in 1984--also known as the Bayh-Dole Act.

In this audit report, we are recommending to the Public Health Service (PHS) that NIH determine if SRI properly reported all patented inventions, and that NIH establish procedures to better monitor SRI's compliance with the Act. The PHS partially concurred with our recommendations. We continue to have concerns with the adequacy of NIH's procedures for determining if similar problems exist at other grantees and detecting on-going noncompliance with reporting requirements.

Background

In Fiscal Year (FY) 1992, NIH, an agency of the Department of Health and Human Services (HHS), awarded about $6.2 billion (26,467 research grants) to universities and nonprofit institutions and private sector organizations (grantees). In FY 1992, SRI received $70 million in grants from NIH. In the 10-year period ending in FY 1992, SRI received almost $471 million (2,138 grants) from NIH. According to SRI's audited financial statements, about 96 percent of SRI's Federal grants were awarded by HHS.

Under the Act, grantees normally have an option to claim title, and patent inventions and technologies developed in whole, or in part, with Federal grant funds. The funding Federal agency maintains the right to restrict title, in exceptional circumstances, to better promote the policy and objectives of the Act. Also, the Federal agency may assert certain rights over the invention. The objectives of the Act are to:

- -- promote utilization of inventions arising from federally supported research and development;
- -- facilitate the commercialization of federally funded inventions by United States businesses and labor, and encourage the maximum participation of small businesses in federally funded research;
- -- ensure grantee inventions are used to promote free competition and enterprise;
- -- promote commercialization and public availability of inventions made in the United States by United States industry and labor; and
- -- ensure the United States obtains sufficient rights in inventions to meet the needs of the Government, and to protect the public against nonuse or unreasonable use of new technologies.

The Act is codified in 35 United States Code, section 200 (35 U.S.C. § 200), and implementing regulations are found at Title 37 Code of Federal Regulations (C.F.R.) Part 401 (37 C.F.R. § 401). The NIH's instructions to grantees are found in the NIH Guide for Grants and Contracts (Guidelines).

When a grantee develops a new technology supported with NIH grant funds, the Act and regulations require grantees to disclose the invention to NIH within 60 days--see 35 U.S.C. § 202(c)(1), and 37 C.F.R. § 401.14. This regulation requires the disclosure be in the form of a written report and be sufficiently complete in technical detail to convey a clear understanding of the invention. The regulations further require the grantee to elect to retain title to the invention within 2 years of disclosing the invention to the granting agency. A patent application with the USPTO must be filed within 1 year after retaining title. If a patent application is filed, a grantee is also obligated to include a statement in the application that the invention was made with Government support--see 35 U.S.C. § 202(c)(6).

The grantee must also provide the Government with a nonexclusive, nontransferable, irrevocable, paid up license to use the invention. According to NIH, the nonexclusive license also allows the Government to obtain the technology or product without paying a royalty, which is normally included in the purchase price of drugs, devices, and other products produced using the new technology.

The Government may assert its rights under 35 U.S.C. § 203 and "march in" and provide a license (the authority to manufacture and sell the product) to an entity other than the grantee that developed the invention. The Government can provide a license to others when the original grantee has not taken (or is not expected to take) effective steps within a reasonable time to achieve practical application[2] of an invention, or when it is necessary to alleviate health or safety needs.

At NIH, monitoring grantee compliance with the Act is the responsibility of the Director, Division of Extramural Invention Reports (Division), in the Office of the Deputy Director of Extramural Research. At the time of our review, the Division consisted of only two people: the Director and an assistant. The Division maintains computerized information on grantees' invention disclosures, elections to take title, and patent applications.

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[2] According to 37 C.F.R. § 401.2, practical application means the manufacture of an invention so that its benefits are available to the public on reasonable terms.

Objective, Scope and Methodology

Our audit was requested by the Chairman, Subcommittee on Regulation, Business Opportunities and Technology (Subcommittee), House Committee on Small Business. The Chairman asked the Office of Inspector General (OIG) to review 130 patents issued to SRI[1] and provide the Subcommittee with an assessment as to whether the Federal involvement in underlying technologies has been properly reported in SRI's patent applications.

To determine if the Federal involvement in underlying technologies has been properly reported in SRI's patent applications, we reviewed pertinent laws, regulations, and NIH policies and procedures which cover this area. We also obtained, from USPTO, a detailed list of patents issued to SRI from January 1979 to March 1993--a period of more than 14 years. We also used Dialog, a sequentially numbered commercial data base that contains data on SRI's patents and is used by patent attorneys and NIH. The Dialog data base showed 125 patents were issued to SRI from January 1979 to March 4, 1993. Both lists contained the names of the scientists/inventors, relevant dates, a description of the patented invention, and whether the patented invention development included Federal funds.

To determine if any of the patents not crediting NIH could have been developed with Federal grant funds, we compared information on the patents to information on a listing of NIH grants awarded to SRI since 1970. We matched the names of inventors and titles on the patents to names of principal investigators and titles on the grants. We reviewed revised invention and patent data that SRI sent to NIH on June 30, 1993. We also performed tests to determine whether NIH had copies of disclosures for inventions related to 43 patents that SRI added the Government rights notice to in June 1993.

Our audit was conducted at the Division, NIH, Bethesda, Maryland, and at the Department of Commerce (DOC) in Washington, D.C. We did not conduct any audit work at SRI. Our audit was conducted in accordance with generally accepted government auditing standards.

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[1] This number was used by NIH officials in testimony given to the Subcommittee and was based on a March 1993 NIH estimate of patents issued to SRI since February 1979.

Results of Our Review

SRI's Patents Did Not Always Disclose Inventions Were Supported with Government Funds

The Act (35 U.S.C. § 202(c)(1) and (6)) requires grantees to disclose the invention to the Government and include in the patent application filed with the USPTO and in the patent that the invention or technology was supported with Federal funds and that the Government has certain rights in the invention. According to 37 C.F.R. § 401.14(f)(4) and NIH Guidelines, grantees are required to include in the patent application and in the patent the following statement:

> "This invention was made with Government support under (grant/contract number) awarded by the (Federal agency). The Government has certain rights in the invention."

We found that SRI was not always including the required statement in its patent applications acknowledging that the invention was developed with Government support and that the Government had certain rights in the invention. Our review of the Dialog data base's 125 patents and those on the USPTO list disclosed that only 51 contained a statement crediting Government funding as required by the Act, 37 C.F.R. § 401.14(f)(4) and NIH Guidelines. Our initial comparison of inventor names and titles on the remaining 74 SRI patents to specific grants awarded to SRI disclosed that many of these patents could also have been supported with NIH grants. For example, we noted in some cases that the inventor shown on the patent was also the principal investigator on NIH grants awarded to SRI, which could have supported research that led to the invention. We requested that NIH review this matter and obtain additional data on inventions from SRI.

According to NIH, an SRI official told the Director of the Division that the reason SRI had credited the Government on so few patents was because it believed that credit should only be given if Government funding could be directly tied to one of the claims on the patent.[4] The NIH informed SRI that this was an erroneous interpretation, and that it must credit the Government if any Federal funds were used in the development of the invention.

The SRI, in a June 14, 1993 letter to NIH, stated that it was reviewing all patents and patent applications and was in

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[4] A claim on the patent application is an assertion regarding the suitability and effectiveness of the invention for a particular purpose.

"...the process of adding the Government rights notice to all patents and patent applications that should have contained the notice." In July 1993, NIH informed us it received new data from SRI related to its review of patents. We examined the new data in August 1993, and found SRI has now determined that the Government should be credited with supporting an additional 43, or 94 of the 125 patents shown on Dialog and USPTO lists. The SRI's new data also included seven additional patents that were not shown on Dialog or the USPTO lists and four patents that were issued after March 4, 1993, the cut-off date for the Dialog data base.

We also found that NIH did not always have records of disclosures related to SRI's inventions, as required by the Act and regulations. The Act and regulations require that when a grantee develops a new technology that was supported with NIH grant funds, it must disclose the invention to NIH within 60 days. We reviewed NIH's files to determine if it had disclosures for the 43 patents to which SRI added the Government's rights notice. We found that NIH did not have records of disclosure for 22 of the subject inventions.[5]

With respect to those SRI patents that SRI determined were developed without Government support, NIH told us it had not yet begun the process of validating SRI's assessment of the Government's involvement.

The NIH Lacks Information to Ensure Compliance with the Law and Regulations

The NIH does not periodically obtain from the USPTO data on patents awarded to SRI. We also found that NIH does not have effective procedures to collect data on SRI's invention disclosures and patents. When grantees develop inventions produced with Federal funds, the law requires them to disclose the invention to the Government, elect whether to take title to the invention, and provide the Government with a nonexclusive license. The Act and 37 C.F.R. § 401.14(f)(4) require grantees to include the Government rights clause in the patent application and the patent.

Information we obtained from Dialog and USPTO showed that SRI had 125 patents and only 51 contained the statement giving the Government credit for supporting the patents. When we first

[5] The NIH may claim title to any invention for which a timely disclosure has not been made--35 U.S.C. § 202(c)(1); 37 C.F.R. § 401.14. By regulation, NIH must exercise this remedy within 60 days of discovery that an agency has failed to make a disclosure. The remedy is a form of intermediate sanction for failure to disclose. It is to be distinguished from the government "march-in rights," through which the government can gain control of useful inventions which the patent-holder is not putting to use--35 U.S.C. § 203, and 37 C.F.R. § 401.6.

contacted NIH in March 1993, it could not locate all the records regarding patents awarded to Scripps that should have credited the Government with supporting the invention.

When we attempted to reconcile this data with files maintained at NIH, the Director of the Division told us that because of the way SRI coded invention disclosures, he was having difficulty matching the data to Dialog's and USPTO's patent lists. We were unable to perform our reconciliation until additional information related to inventions and patents was obtained from Scripps several months later.

Conclusion and Recommendations

When the Government is not aware of a grantee's invention, it is not able to exercise its rights and to protect the taxpayers' interests. For instance, the Government retains rights through a nonexclusive license to use the invention, and the right to restrict title, in exceptional circumstances, to better promote the policy and objectives of the Act. Also, according to NIH and DOC officials, the Government has the right to obtain the technology without paying a royalty, which is normally included in the purchase price of the product. If the Government is unaware of situations where it might obtain nonexclusive licenses, it may be missing opportunities for savings on purchases of medical supplies or devices.

The SRI did not always comply with reporting requirements found in 37 C.F.R. § 401, and NIH instructions found in the NIH Guidelines. Also, NIH has not compared grants awarded to SRI and patents issued to SRI to determine the validity of SRI's claim that a number of its patents were developed without the support of Federal funds. The NIH also has not taken the necessary steps to establish procedures and systems that ensure that SRI discloses inventions to NIH, and includes the statement of Government support on patent applications. We believe that NIH's management of this area could be improved if it obtained patent data from the USPTO and Dialog and maintained systems that compared and reconciled this data with information provided by SRI and other research organizations. Without such information, NIH is not in a position to determine whether the objectives of the Act are being met with regard to sponsored activities.

We also conclude that additional review is warranted concerning the adequacy of SRI's disclosure of inventions to NIH, and the effectiveness of NIH's remedy where necessary disclosures are not made.

With regard to SRI and other grantees, we recommend that you have NIH:

1. examine the remaining patents SRI claims were not developed with the help of Federal funds and determine if SRI's assessment of the Government's involvement is correct;

2. determine the extent of noncompliance by other grantees with reporting requirements found in 37 C.F.R. § 401, and NIH Guidelines; and

3. develop procedures to obtain from USPTO information on patents issued to NIH grantees. The Division of Extramural Invention Reports should determine whether such patented inventions were supported by NIH funds.

Other Matters

The OIG, in May 1994, issued a final report (OEI-03-91-00930) on NIH's oversight of grantees' compliance with the requirements of the Bayh-Dole Act. The inspection was unrelated to the Subcommittee's March 15, 1993 request for an audit of SRI's activities. The inspection found, in part, that NIH lacks a systematic process for ensuring that grantees submit required invention information, and that NIH has limited its oversight of grantees by not requiring that grantees document compliance with Federal regulations. The inspection also found that NIH does not fully utilize its invention data base to monitor grantees. The report recommended NIH re-examine its oversight role, add more detailed information to its data base, and use it to track grantee compliance.

Agency Response and OIG Comments

On May 24, 1994, the PHS responded to the recommendations in our draft report. The PHS partially concurred with our recommendations. We continue to have problems with NIH's procedures for assuring that its grantees are in compliance with reporting requirements. The recommendations, a summary of PHS' response to each recommendation and, where applicable, our comment on PHS' response are presented below. The PHS response is included in its entirety as an Appendix to this report.

With regard to our first recommendation that PHS have NIH examine the remaining patents SRI claims were not developed with the help of Federal funds and determine if SRI's assessment of the Government's involvement is correct, PHS

concurred. It said that it is reviewing 35 patents that SRI stated were not funded with Government support. According to NIH, preliminary results show that 11 of the 35 were developed with Government support. The NIH expects to complete its review of these patents and issue an opinion regarding Government involvement by December 31, 1994.

With regard to our second recommendation that PHS have NIH determine the extent of noncompliance by other grantees with reporting requirements found in 37 C.F.R. § 401, and NIH Guidelines, PHS said it concurred with the intent of our recommendation and stated it has taken steps to enhance its oversight capabilities to ensure grantees comply with reporting requirements. The PHS stated NIH is developing a new system to track inventions reported to it by grantees and stated it intends to coordinate information on technology transfer now maintained by the Association of University Technology Managers (AUTM).

We do not believe that NIH's actions will allow it to determine compliance with reporting requirements. The PHS did not state how NIH will use the AUTM data to determine the extent of grantee noncompliance with current reporting requirements. Our understanding is that AUTM's data on inventions, patents and licenses is obtained on a voluntary basis from universities and others. If a grantee does not disclose an invention or patent to PHS or to AUTM, NIH will have no way of determining grantee compliance with reporting requirements of the Act.

We believe NIH should maintain information on patents awarded by the USPTO. The NIH could investigate those grantees which, based on a review of the data from the USPTO, appear to be underreporting inventions to NIH. For example, NIH might review the USPTO patents of selected grantees and investigate those that show an unreasonably low percentage of their patents were developed with Government funds.

Finally with regard to our third recommendation that PHS have NIH develop procedures to obtain, from the USPTO, information on patents issued to NIH grantees and that the Division of Extramural Invention Reports should determine whether such patented inventions were supported by NIH funds, the PHS stated that it concurred with our recommendation if the intent of the recommendation was for NIH to validate USPTO data to NIH files when the Government rights clause is included on the patent. The PHS stated it does not agree with our recommendation if the intent of the recommendation requires NIH to validate USPTO data against NIH data for all grantee patents not indicating Government support. The PHS claims that the latter would require too much work.

We disagree with PHS. If NIH only validates USPTO data when the Government clause is included in the patent, it will not detect underreporting similar to that which existed at SRI. Our recommendation is intended to suggest an approach that would allow NIH to identify those cases where inventions should have been reported and the rights clause included in the patent; but were not. With respect to NIH's position that our recommendation would require too much work, we suggest that NIH might use as risk-based approach that would ensure that those grantees most likely to have inventions and file for patents are reviewed.

We would appreciate being advised within 60 days of the status of corrective actions taken or planned on each recommendation. If you have any questions, please call me or have your staff contact Michael R. Hill, Assistant Inspector General for Public Health Service Audits, at (301)443-3582.

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES

APPENDIX
Public Health Service

Memorandum

Date MAY 24 1994

From Assistant Secretary for Health

Subject Office of Inspector General (OIG) Draft Report "Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute," A-15-93-00029

To Inspector General, OS

Attached are the Public Health Service comments on the subject draft report. We concur with the report's recommendations. The actions taken or planned to implement these recommendations are described in the comments.

Philip R. Lee, M.D.

Attachment

IG	
SAIG	✓
PDIG	
DIG-AS	✓
DIG-EI	
DIG-OI	
AIG-MP	
OGC/IG	✓
EXSEC	
DATE SENT	5-25

PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT "UNDERREPORTING FEDERAL INVOLVEMENT IN NEW TECHNOLOGIES DEVELOPED AT THE SCRIPPS RESEARCH INSTITUTE," A-15-93-00029

General Comments

The National Institutes of Health (NIH) awards over 28,000 research grants and about 1,400 contracts to approximately 1,700 non-profit organizations, universities, hospitals, and businesses each year. In comparison with the number of awards made, the total number of inventions developed is relatively small (approximately 10,000 total invention disclosures in the past 15 years).

The Bayh-Dole Act (Act) facilitates the utilization of inventions arising from Federally-supported research; transfer of technology to promote free competition and enterprise; and rights of the Government in protecting the interests of the public. NIH will take steps to increase the effectiveness of compliance with the Act through education efforts directed to recipients of NIH funding, improved reporting procedures, and oversight that is consistent with a purpose of the Act (35 United States Code § 200) to minimize the costs of administering policies in this area.

OIG Recommendation

We recommend that NIH:

1. Examine the remaining patents SRI [Scripps Research Institute] claims were not developed with the help of Federal funds and determine if SRI's assessment of the Government's involvement is correct.

PHS Comment

We concur. NIH is in the process of reconciling 35 SRI patents to determine if the Government supported their development. Preliminary information indicates that 11 were developed with Federal support and 24 were developed without Federal funds. Of the 11, one was a fellowship grant which is exempt from reporting under the Act's implementing regulations [37 C.F.R. § 401.1(b)]; eight were funded by NIH grants issued before the passage of the Act when it was not a requirement that a Government support clause be added to a patent application; and the remaining two are still under review.

The NIH expects to complete its review of these patents and issue an opinion on SRI's assessment of the Government's involvement by the end of calendar year 1994.

OIG Recommendation

2. Determine the extent of noncompliance by other grantees with reporting requirements found in 37 C.F.R. § 401, and NIH guidelines.

PHS Comment

We concur with the objective of this recommendation and have taken steps to enhance the oversight capabilities of the NIH's Division of Extramural Invention Reports (DEIR) to ensure grantees' compliance with the reporting requirements of 37 C.F.R. § 401. DEIR is developing a new computer system that will augment its ability to determine compliance with reporting requirements.

This system will allow grantees to transmit reports electronically, thereby increasing the timeliness and accuracy of the reports while reducing paper transactions. Electronic transmittal will also improve the accessibility of the data in a form readily available for analysis and reports. The improved database will facilitate follow-up actions on invention disclosures to determine if subsequent patents contain appropriate clauses to protect Government rights, as well as information on waivers, licensing and utilization. Finally, electronic reporting will be much more cost effective for both the recipient and the Government, a goal of the Act. It is expected that this electronic transfer mechanism will become operational in Fiscal Year 1995.

The DEIR also intends to coordinate, with the Association of University Technology Managers (AUTM), the exchange of information of mutual interest on technology transfer. For example, the AUTM Licensing Survey, which is updated each year, provides the most recent statistics on licensing activities from universities, hospitals, research institutes, government agencies, and third-party patent management firms. It reports on discoveries or inventions that have been licensed within the past 10 years and are currently on the market generating sales. It covers such topics as sponsored funding amounts, licensing activity, gross royalties received, and statistics on invention disclosures and patent filings.

The AUTM is conducting a follow-up survey entitled "AUTM Public Benefits Survey." A summary report, developed from survey data, will identify concrete examples demonstrating that U.S. institutions are carrying out the mandate, and achieving the goals of the Act.

OIG Recommendation

3. Develop procedures to obtain from the USPTO [United States Patent and Trademark Office] information on patents issued to NIH grantees. The DEIR should determine whether such patented inventions were supported by NIH funds.

PHS Comment

We concur with this recommendation if OIG envisions NIH developing the capacity to obtain USPTO information on patents to NIH grantees and, in cases where Government support is acknowledged, cross-check DEIR records with USPTO information on disclosure and subsequent reporting on waivers, licensing and utilization. Such a process may assist in identifying patents that had not been properly disclosed in the first place. In the long-term, NIH can develop such a capacity.

However, we do not concur with this recommendation if it suggests an identification of patents to organizations in cases where there has been no acknowledgement of Government support. This implies that NIH would identify patents issued to organizations that happen to be recipients of NIH funds and confirm whether NIH may have supported the development of the activity. This is a far more complex undertaking than matching database records between the USPTO and NIH. To begin with, it would require a cross-walk between data elements in the patent and in NIH databases. In the event of matches, there would need to be a determination by NIH program staff that a close enough fit exists to suggest that the patent may have been developed under NIH support. There would then need to be an inquiry to the organization, various analyses, and a final determination.

Implementation of a process like that just described would result in an enormous burden that we believe would show little gain in compliance, and not be consistent with the Act.

Applicable HHS IG Reports

Report Title

- Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute (6/94)
- NIH Oversight of Extramural Research Inventions (5/94)

1.

Background

NIH		
Fiscal Year	**Research Grants**	**Amount Awarded**
1992	26,467	$6.2 Billion
1993	29,529	$7.3 Billion

2.

Patent and Trademark Amendments Act

Objectives

The goal of the Bayh-Dole Act is comprised of seven objectives. These objectives are to:

1. Ensure the U.S. obtains sufficient rights in federally supported inventions to meet its needs and protect the public against nonuse or unreasonable use of inventions;

2. Promote utilization of federally supported inventions;

3. Encourage maximum participation of small business firms in federally supported research and development efforts;

Patent and Trademark Amendments Act (Continued)

Objectives

4. Promote collaboration between commercial concerns and nonprofit organizations, including universities;

5. Ensure grantee inventions are used in a manner to promote free competition and enterprise;

6. Promote commercialization and public availability of inventions by U.S. industry and labor; and

7. Minimize administrative costs.

4.

Background

NIH Grants to Scripps	
Fiscal Years	**Amount Awarded**
1993	$74.9 Million
1984 -1993	$521.0 Million

5.

Grantee Obligations

- Disclose inventions within 60 days
- Elect whether to retain title -- within 2 years of disclosure
- File patent application within 1 year after retaining title
- Include Government Rights Clause in patent application
- Provide Government a nonexclusive license

6.

Audit Finding

- 125 patents were issued to Scripps 1/79 to 3/93
  - ✔ 51 had the statement giving the Government credit for patent support as of 4/93
  - ✔ 43 more were identified by Scripps in 6/93

7.

Audit Conclusion

- Scripps patents did not always disclose inventions were supported with Government funds.

8.

Audit Finding

- NIH did not detect that Scripps underreported the number of patents that should have contained the Government Rights Clause.

9.

Audit Conclusion

- Because NIH was unaware of patented inventions Scripps developed with NIH funds, NIH can not assure that the objectives of the act are being met.

10.

Inspection Finding

- NIH lacks a systematic process for ensuring that grantees submit all required invention information
  - ✔ NIH does not review invention disclosures and elections of title for timeliness and does not know if grantees are in compliance.
  - ✔ NIH does not examine annual utilization reports to monitor grantees' commercialization efforts.
  - ✔ NIH has no system to ensure timely filing of patent applications.

11.

Inspection Finding

- NIH does not fully utilize its invention database to monitor grantee compliance.
- NIH has the primary role in ensuring its grantees comply with Federal regulations for inventions.

12.

OIG Recommendations

NIH Should Examine remaining patents Scripps claims were not developed with Federal funds and determine if Scripp's assessment is correct;

NIH Should Determine extent of noncompliance by other grantees with CFR reporting requirements and NIH guidelines;

13.

OIG Recommendations (Continued)

NIH Should Develop procedures to obtain USPTO information on patents issued to grantees, and determine whether such inventions were supported by NIH funds.

NIH Should Improve monitoring of grantee compliance with Bayh-Dole requirements.

NIH Should Collect more detailed licensing and utilization information and track grantees for timely compliance.

14.

OIG Concern

- When the Government is not aware of a grantee's invention,
  - ✔ the Government is not able to exercise its rights;
  - ✔ the Government is not able to protect the taxpayers' interests; and
  - ✔ the Government is not able to ensure that other Bayh-Dole objectives are being met.

15.

FOR RELEASE ON DELIVERY

Statement of

Wendy Baldwin, Ph.D.

Deputy Director for Extramural Research
National Institutes of Health
Department of Health and Human Services

before the

Subcommittee on Regulations,
Business Opportunities, and Technology
of the
Committee on Small Business
U.S. House of Representatives

July 11, 1994

Mr. Chairman, I am pleased to appear before the Subcommittee on Regulations, Business Opportunities, and Technology this morning on behalf of Dr. Harold Varmus, Director, National Institutes of Health (NIH) to discuss implementation of the University and Small Business Patent Act of 1980, Public Law 95-517, (Bayh-Dole Act) at the NIH. We have read the Office of the Inspector General (OIG) report and share your concerns about the protection of Federal rights to technologies made under NIH funding agreements. My testimony today will provide the Subcommittee with information on the Bayh-Dole Act, the steps NIH is taking to meet the requirements of the Act, and the actions NIH is implementing to improve invention reporting by our grantees.

BACKGROUND

Following World War II, the government recognized the national benefit of investing in biomedical research. Since that time, Federal funding for research increased dramatically to government laboratories and universities across the country and significant discoveries were being made to improve the health and well-being of the nation. Nonetheless, concern was also being expressed about the government's lack of a consistent government-wide patent policy and the generally restrictive nature of this policy. The government was reluctant to give up the ownership of Federally-funded inventions to universities or other grantees. For this reason, it was general policy that grantees were only permitted non-exclusive licenses. This provided no incentive for grantees to

invest in the development of an invention since competitors could obtain a license from the government once the invention is commercialized and sell/manufacture the invention with little investment of capital. This disincentive to commercialize government-assisted inventions is clearly evidenced by the fact that in 1980, the Federal government owned 30,000 patents and only 5% led to new or improved products.

To improve the transfer of technology to the private sector, the Bayh-Dole Act was passed in 1980 giving grantees the right to obtain title to inventions resulting from their Federally-funded research and to license such inventions to commercial entities for development. The objectives of the Act are to:

- Promote collaboration between commercial concerns and nonprofit organizations, including universities;
- Promote the utilization of inventions arising from Federally supported research or development;
- Encourage maximum participation of small business firms in Federally-sponsored research and development efforts;
- Ensure that inventions made by nonprofit organizations and small business firms are used to promote free competition and enterprise;
- Promote the commercialization and public availability of inventions made in the United States (U.S.) by U.S. industry and labor;

- Ensure that the Government obtains sufficient rights in Federally-sponsored inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of the invention; and
- Minimize the cost of administering policies in this area.

The impact of the Bayh-Dole Act goes beyond providing additional economic benefit to just universities and small businesses receiving Federal support. The economic benefit extends to the nation as a whole. According to Dr. Alan Goldhammer of the Biotechnology Industry Organization, the enactment of the Act has led to 1000 new companies and creation of about 100,000 new jobs. The biotechnology industry continues to expand. In a 1993 survey by the Association of University Technology Managers universities and hospitals inventions generated 2833 licenses and options. Clearly, the Bayh-Dole Act is providing a positive national economic benefit with its multiple incentives for grantee institutions to move products to the marketplace.

THE BAYH-DOLE ACT

The Bayh-Dole Act, as amended, permits nonprofit institutions, small businesses, and contractors that receive Federal funds to retain title to Federally-funded inventions and encourages them to commercialize inventions. Under Bayh-Dole, the government retains a nonexclusive, nontransferable, irrevocable, paid-up license to

practice or have practiced for or on behalf of the United States any subject invention throughout the world.

An agency can limit the grantee's/contractor's right to take title only through a written determination that exceptional circumstances exist such that the policy and objectives of the Bayh-Dole Act would be better promoted by restricting or eliminating this right. The Public Health Service (PHS) and the Department of Energy are apparently the only agencies that have used the exceptional circumstances provision. The PHS cases have involved situations where a contractor was screening or manufacturing proprietary third party compositions and the third parties were understandably concerned that the contractor would be able to patent a novel use of their proprietary composition. Without exceptional circumstance protection, drug firms are extremely reluctant to participate in NIH screening programs.

In addition to the exceptional circumstance provision, the Bayh-Dole Act includes "march-in" rights which allow the Federal funding agency to require the grantee/contractor (or its assignee or exclusive licensee) to grant licenses to responsible applicants, if necessary, under certain circumstances. In extreme cases, the government has the right to grant such licenses itself, when, for example, effective steps have not been taken, or is not expected to be taken, within a reasonable time to achieve practical application of an invention or such action is necessary to alleviate health or

safety needs or to meet the requirements for public use. To date, while the NIH has on occasion threatened to use "march in" rights with some positive results, it has never fully exerted its "march-in" rights, nor are we aware of any other Federal department that has formally exercised these rights.

WORKING WITH THE DEPARTMENT OF COMMERCE

The NIH is a member of an interagency group chaired by the Assistant Secretary for Technology Policy for the Department of Commerce. The purpose of this group is to address policy issues concerning the Bayh-Dole Act. In addition to this interaction, the NIH has taken a positive and assertive role in promoting better understanding and consistency in implementing the Act.

On September 29, 1993 the NIH invited members of several Federal agencies most of whom work in the technology transfer area including the Department of Commerce to a meeting to discuss the degree and kind of oversight each federal agency brings to implementing technology transfer regulations. The NIH learned that most agencies preferred better education of the entire community and improved dissemination of information over a primarily regulatory approach. Furthermore, for the most part, other agencies do not conduct case-by-case oversight as recommended by the OIG.

In addition, on January 25 and 26 of this year, the NIH convened an outside panel of experts in a public forum to explore and further define issues arising from sponsored research agreements between NIH grantee institutions and industry. The input from the panel and other participants in the public forum promulgated guidelines or "points to consider" when drafting sponsored research agreements with industry. The intent of these guidelines were to assist grantees in ensuring that sponsored research agreements comply with the requirements of the Bayh-Dole Act and NIH funding agreements while upholding basic principles of academic freedom.

The NIH, as a member of the Federal Demonstration Project (FDP) which involve members from 12 Federal research agencies including the Department of Energy, the Office of Naval Research and the National Science Foundation, and approximately 50 universities, plans to invite the Department of Commerce to join us at the FDP meetings in a Federal-wide effort to develop consistent invention reporting procedures and ensure that any procedures that are developed are in agreement with the regulation and patent filing procedures. The FDP is sponsored by the Government University Industry Research Roundtable for the purpose of developing cost-effective research administration. This forum has been successful in standardizing certain administrative procedures among research agencies. The NIH has requested that this issue be place on the next FDP meeting agenda.

IMPLEMENTATION OF THE BAYH-DOLE ACT IN THE NIH EXTRAMURAL PROGRAM

Each grantee or contractor is required to report an invention within 60 days from the time an investigator discloses an invention which has been conceived or first actually reduced to practice under an NIH funding agreement. This requirement is supplemented by instructions to investigators to report inventions as part of the annual progress report for the period of their noncompetitive NIH support and whenever they apply for competing renewal of support. A invention report is one of three required reports that are due 90 days after the end of a project. With each of these reports, the investigator must notify NIH whether or not an invention was made with NIH funds.

All reports identifying an invention are immediately referred by NIH awarding units to the Extramural Invention Reports Office (EIRO). These reports are used to reconcile the detailed invention disclosures which are reported independently to EIRO. If a full invention disclosure, complete in technical detail, has not been made to the EIRO, grantee institutions are notified. This system of cross-referencing helps guard against omissions in reporting.

The NIH Guide for Grants and Contracts with a weekly circulation of 34,000 is the primary conduit for disseminating information between the NIH and all of its grantees and contractors. We have used the Guide to rapidly inform our extramural community of requirements, responsibilities and new policies concerning inventions. Examples

include the June 22, 1990 and the October 23, 1992 issues that explained the requirements associated with inventions, the proper procedures to ensure compliance and copyright and royalty income.

The NIH is in the process of reviewing our reporting systems further to ensure that institutions have appropriately reported all inventions made under NIH funding agreements. To this end, the OIG and NIH staff have both reviewed information in the commercial patent database DIALOG and analyzed the proportion of Federally-supported patents to the total number of patents issued to a given organization. Some of these proportions appear low in light of the total Federal funding. As a pilot project to further evaluate reporting compliance, we have contacted 20 institutions to reconcile our records with theirs and to provide additional utilization information. Fifteen of these institutions are among those that report the greatest number of patents supported by Federal funding agreements and their responses will help to determine the completeness of their previous reporting. Five of the institutions report few patents with Federal support even though they are among our top 100 recipients. Their responses will assist us in confirming that there were, in fact, few patents developed with NIH support at these institutions. An analysis of the patterns of responses from these institutions will be presented at the November NIH Regional Grants Management Seminar which, typically has 250 or more research administrators and faculty in

attendance. Through discussions with the community at large, we can determine whether further modification of our procedures is needed.

EXPANSION AND IMPROVEMENTS TO THE NIH EXTRAMURAL INVENTION REPORTING DATABASE

We are already making substantial improvements in our basic record system and database. For example, the NIH is implementing a new Invention Status Reporting System that will improve and expand the invention disclosure database and permit the generation of regular reports; and will directly link our grantees/contractors to our database, allowing personal computer-based data entry. New computer hardware and software have been ordered that will increase our capability to record, organize, and generate information reports. The system will generate follow-up queries to institutions that disclosed inventions, but did not inform us within the required time period about election of title, or provide us with information on patent applications or request for waiver of rights to title.

This initial reporting must be conducted invention by invention as the grantees proceed through the patent process with attention to the important time milestones, the confirmatory license to the government and the clause regarding Federal royalty-free use by the government. However, utilization information concerning licenses, waivers for foreign manufacture of products of inventions for U.S.

sale or use, preference for small business, and royalties can shift to an institutional report that is done just once a year providing specific utilization information about each patent. A report of this kind will establish an annual institutional review of all patent activity and help identify any inadvertent omission of reports of individual inventions, patent applications or patents. Additionally, the institutional official will provide a written assurance as part of each report that there were no other inventions, patent applications or patents conceived or first actually reduced to practice in the performance of work under an NIH funding agreement. This assurance will cite the appropriate references to the False Claims Act, the Civil Remedies Act and other applicable statutes and will help achieve cost-effective compliance with the requirements for disclosure and subsequent reporting.

In the spirit of "reinventing government", we believe that we can convert this system of reports to a direct, on-line, electronic communication process in the near future. Grantees/contractors will provide both individual invention reports and institutional utilization reports electronically, thereby reducing the total paperwork and increasing the accuracy of the report system. An electronic system will benefit both grantees and the NIH by 1) building in oversight questions that will verify compliance with regulations and 2) eliminating a significant amount of paper transfer and duplication of data entry. We will develop this

system in conjunction with institutional representatives and professional associations. We believe electronic data entry and communication with our grantees will significantly improve compliance. In addition, we also realize that streamlined, consistent Federal agency procedures promote compliance.

OUTREACH AND EDUCATION

Through its many contacts with investigators and institutional officials, the NIH believes that many situations of noncompliance are due to a misunderstanding of requirements and expectations. We are increasing our efforts to educate and inform the research community about the requirements of the Bayh-Dole Act. We intend to publish an announcement of the concerns that have been identified in the OIG review and any subsequent findings from our inquiries with the 20 sample institutions. In addition we will continue work with professional organizations, such as the Council on Governmental Relations, the Association of Independent Research Institutes, the Association of University Technology Managers, the Society of Research Administrators, the National Council of University Research Administrators, and other appropriate organizations to communicate the requirements of the Act and the procedures that are necessary to assure compliance.

SCRIPPS RESEARCH INSTITUTE

Like the OIG we are concerned about the under-reporting by Scripps Research Institute on the number of patents that had been developed

with Federal support. Within the last year, Scripps has updated their reports to NIH and the number of NIH supported patents during the period January 1979 to March 1993 has increased to 94.

We believe that Scripps has now accurately reported to the NIH all patents that were developed with Federal support. We wrote to Scripps on July 6 and asked that they either certify to us that there were no other patents developed in part with Federal support during the period of review that should be reported to us, or report any additional patents that were not previously reported. We believe that these steps resolve the concerns about under-reporting by Scripps and that we can now rely on the improvements that we are making in our routine reporting system to assure their compliance in the future.

CONCLUSION

In conclusion, we are taking assertive steps to improve our own capacity to monitor the invention reporting system and we will work closely with the research community to further improve compliance with the provisions of the Bayh-Dole Act. Nonetheless, the fundamental objectives of the Act have been achieved. The real success story is that the results of Federal research, in general, and biomedical research, in particular, are being effectively transferred to the private sector for development, thereby, improving the nation's economic health as well as its citizen's health. We will continue to do our part to ensure this success.

This completes my testimony, Mr. Chairman. I will be glad to answer any questions you or members of the Committee may have.

Statement of

Dr. William H. Beers
Senior Vice President

and

Douglas A. Bingham
General Counsel

The Scripps Research Institute

before

The Subcommittee on
Regulation, Business Opportunities, and Technology
of the
House Committee on Small Business
103d Congress, Second Session

July 11, 1994

Mr. Chairman and members of the Subcommittee, I am William Beers, Senior Vice President of The Scripps Research Institute. With me this morning is Douglas Bingham, Scripps' General Counsel. We welcome this opportunity to speak with you about the report of the Inspector General of the Department of Health and Human Services concerning invention reporting at Scripps and, more generally, to share with you Scripps' thoughts concerning invention reporting by nonprofit research institutions.

Scripps is one of the world's largest nonprofit biomedical research organizations not affiliated with a university. We are flattered that the Chairman has characterized Scripps as one of America's "biomedical research crown jewels." We have more than 200 scientists on our faculty and approximately 500 post-doctoral fellows. Their work is reported in some 500 scientific publications annually.

Scripps receives financial support from a number of sources, including individuals, foundations, pharmaceutical and other companies, and of course, the U.S. Government. Last year, Scripps' funding under grants from the National Institutes of Health ("NIH") totalled approximately $74 million. These grants accounted for nearly 60% of Scripps' revenues.

In March 1993, the Subcommittee's Chairman and Ranking Minority Member asked the Inspector General of the Department of Health and Human Services to audit the patents issued to Scripps during the previous ten years to determine whether Government sponsorship of the underlying research had been duly reported. That request prompted a year-long investigation by the Inspector General into Scripps' compliance with the invention reporting requirements of the Bayh-Dole Act, which governs the rights of the Government and of nonprofit organizations like Scripps in inventions made with Government funding. The investigation ultimately led to the June 15, 1994 Inspector General report that you asked us to address this morning.

Rights in Inventions Made under Government Grants

Before turning to the details of the Inspector General's Report, it might be useful to review just briefly the structure of the Bayh-Dole Act.

Under the Act and its implementing regulations, each invention made with Government funding must be reported to the Government by the grantee institution within two months of the time it becomes known to the institution's personnel responsible for the administration of patent matters. The Act then permits the grantee institution to elect to retain title to the

invention. In order to retain title, a grantee must seek patent protection for the invention and take effective steps to achieve practical application of the invention.

When a grantee retains title to a Government funded invention, the Government receives a nonexclusive royalty-free license to use the invention for Government purposes. To ensure that the Government and third parties are aware of the Government's license rights, the Bayh-Dole Act requires each patent covering such an invention to include a notice that the patented invention was made with Government support. We call such a notice a "sponsorship statement."

The Inspector General's Report

The Inspector General found that Scripps' patents did not always contain the required sponsorship statements. Specifically, the Inspector General found that Scripps had failed to include such statements in 43 patents covering Government funded inventions. We accept this finding of the Inspector General and acknowledge these errors of omission, errors we should not have made.

We assure you, however, that these errors were just that -- inadvertent, unintentional mistakes. Scripps derives no benefit from omitting such

sponsorship statements. And as we will soon discuss, we are pleased that the Government suffered no injury from these omissions.

Scripps is committed to ensuring that such mistakes do not happen again. Indeed, even before the Inspector General's investigation began, Scripps was conducting a comprehensive review of all of its invention disclosures and patents. As a result of this review, by June 30, 1993, Scripps had added sponsorship statements to all of its existing patents and pending patent applications as required by the Bayh-Dole Act. In addition, Scripps provided NIH with a complete set of the required documentation for each existing Scripps patent covering an invention made with NIH support. Thus, we addressed over a year ago all of the deficiencies cited in the Inspector General's report.

The Inspector General's report raises the question whether sponsorship statements should be added to any of Scripps' 35 patents that do not now contain them. Scripps believes that each of these inventions either was made without Government funding or that no sponsorship statement was required for other reasons. The comments of the Public Health Service on the Inspector General's report indicate preliminary agreement with our conclusion with respect to 33 of these patents. NIH still is studying the other 2

Scripps patents, and Scripps will cooperate fully in that inquiry.

The only other comment made by the Inspector General regarding Scripps' inventions is that before June 1993, NIH did not have disclosure records for 22 NIH funded inventions for which Scripps had obtained patents.

Because we do not have access to NIH's records, we cannot comment on what they might contain. However, we reviewed our disclosure records against a list of Scripps patents provided to us by the Inspector General's office in response to our request. Our comparison suggests that of the 21 patents on the list, Scripps had submitted disclosures to NIH corresponding to all but six of them. We have been unable to verify whether disclosures for those six were provided to NIH, but they related to inventions disclosed to Scripps' Office of Technology Transfer ("OTT") between 1981 and 1987, the years immediately following enactment of the Bayh-Dole Act. Thus, while Scripps may have patented some Government funded inventions without disclosing them to NIH, we believe that such mistakes were made in a relatively small number of cases.

In retrospect, it is clear that we at Scripps have done better at making inventions than at reporting them. The regulations that govern the reporting of

Government-funded inventions are complicated. There are many requirements to be met and fairly rigid time periods in which to do so. Perhaps some of Scripps' invention reporting deficiencies could have been avoided if we had devoted greater resources and attention to our OTT.

However, our record of compliance appears to have improved over the years, and we are taking additional steps to improve our compliance in the future. We certainly regret the past deficiencies in our invention reporting.

Effect of Deficiencies Cited by the Inspector General

While Scripps wishes that it had not made the mistakes we just described, we hasten to add that we believe that these mistakes did not harm the Government or the public in any way.

As we have described, the Bayh-Dole Act gives the Government certain rights with respect to inventions to which grantees retain title. Probably the most important of these is a nonexclusive royalty-free license to practice the invention for Government purposes and the right, in certain circumstances, to "march in" and direct that the invention be licensed to others. These rights belong to the Government as a matter of law; they could not be "lost" as a result of a

belated disclosure by Scripps or a failure to include sponsorship statements in certain patents.

One purpose of these sponsorship statements is to notify the Government that it can invoke certain provisions of the Federal Acquisition Regulation, or "FAR," which ensure that when the Government buys products, it does not pay royalties for the use of patented technology in which it has a royalty-free license. Even though Scripps neglected to include all of the required sponsorship statements, however, the Government was not prejudiced.

-- If the Government itself practiced any Scripps patents from which sponsorship statements were omitted, it did not pay compensation to Scripps for doing so.

-- If the Government procured any products covered by Scripps patents, we are not aware of it. Scripps does not have detailed information about particular sales made by its licensees, so we would not necessarily know of such sales. However, we do know that sponsorship statements were not improperly omitted from a single Scripps patent covering a commercially available product.

Thus, we are confident that neither the Government's nor the public's interests were prejudiced in any way by the mistakes Scripps made in reporting its inventions.

Corrective Measures Taken by Scripps

Scripps not only has corrected its past mistakes in meeting Bayh-Dole Act obligations but also has taken a number of steps to minimize the risk of similar errors in the future.

-- First, Scripps has begun to account for all invention disclosures on a monthly basis to ensure that no inventions "slip through the cracks" and that Bayh-Dole time deadlines are met.

-- Second, Scripps has begun providing to NIH in a single package every month all disclosures of NIH funded inventions received by Scripps' OTT, as well as other documents required by the Act. We believe that the discipline of monthly reporting will minimize the risk of inadvertently failing to report an invention.

-- Third, monthly reports to NIH and all Scripps patent applications are now reviewed and approved by at least two administrators familiar with Bayh-Dole Act requirements in addition to the person who prepared them.

-- Fourth, Scripps has expanded the briefing provided to new faculty members to ensure

that they fully understand applicable invention disclosure requirements. Of course, Scripps' OTT and General Counsel's office always are available to answer questions about invention reporting that might arise.

-- And, finally, on an annual basis commencing this fall, Scripps will conduct an internal audit of its compliance with Bayh-Dole Act requirements. This audit will be supervised by the General Counsel and reported to the Senior Vice President who oversees Scripps' OTT.

Invention Reporting Policy Matters

The Chairman's letter inviting us to speak today raised a number of more general questions about the reporting of inventions made with Government funding.

At the outset, we must note that Scripps is a biomedical research institute. Our expertise is in science, not government. But with that caveat, we would be pleased to share our views on these matters.

As to how widespread the problem of noncompliance with Bayh-Dole Act reporting requirements may be, we have no factual basis for drawing any conclusions. We simply do not know the extent to which other

institutions satisfy Bayh-Dole Act requirements. The only information we have is anecdotal, and that information suggests that the kind of inadvertent errors made by Scripps are not uncommon. Press accounts also suggest that other grantees have made similar errors. However, we defer to others more knowledgeable about these matters for a more informed response.

The Chairman asked our views on oversight of invention reporting compliance by NIH grantees. Although we claim no particular expertise in regulatory enforcement, we believe that NIH, and not some other agency, should oversee the compliance by NIH grantees with invention reporting obligations, just as NIH oversees its grantees' compliance with other conditions of their grants. Indeed, NIH is probably the only agency with the scientific expertise necessary to evaluate and track the invention disclosures filed by its grantees.

We recognize that NIH's Division of Extramural Invention Reports has been criticized for its oversight of grantees. We can certainly understand, however, why the Division might have encountered problems. When one considers that the Division must monitor the activities of approximately 1,700 organizations that receive nearly 30,000 NIH grants and contracts each year, it is not

surprising to hear that it sometimes has had difficulty keeping up with the volume of work it faces.

Suggestions for Improvement

In connection with the Inspector General's investigations, we have taken a close look at Scripps' invention reporting and management practices. We thought we might conclude our remarks today with a few general observations about improving these practices throughout the grantee community.

-- To the extent that grantee institutions have not implemented invention reporting and tracking practices like those recently implemented by Scripps, they might consider doing so.

-- Grantee institutions would benefit greatly from NIH-sponsored workshops for OTT personnel instructing them in Bayh-Dole Act reporting requirements, suggesting effective procedures for ensuring compliance, and answering questions that commonly come up.

-- Currently, NIH does not provide acknowledgment of its receipt of invention reports and other required documents. If it did so, grantee institutions would have

greater assurance that NIH's records are consistent with their own.

-- Increasing the staffing of NIH's Division of Extramural Invention Reports would allow it to carry out our suggestions as well as do a more effective job of overseeing compliance by grantees.

-- Finally, invention reporting would be less burdensome for grantee institutions, and inventions could be tracked more effectively, if grantees could file required documents electronically. This would be an important capability to develop in connection with NIH's Electronic Research Administration initiative.

* * *

Mr. Chairman, we hope you have found this information useful. We would be pleased to answer any questions you might have.

Comments on the Need for Better Federal Government
Oversight of Taxpayer Supported Research and Development

before the

Subcommittee on Regulation, Business Opportunities and Technology
of the Committee on Small Business, U.S. House of Representatives

James P. Love
Director, Economic Studies
Director, Taxpayer Assets Project
Center for Study of Responsive Law

July 11, 1994

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I. Introduction

Thank you for the opportunity to appear today to discuss the need for better federal government oversight of taxpayer supported research and development. My name is James P. Love. I work for the Center for Study of Responsive Law, where I am the Director of Economic Research, and also the Director of its Taxpayer Assets Project (TAP).

The Center for Study of Responsive Law is a non-profit organization which was created in 1968 by Ralph Nader to conduct research on a wide range of public policy issues. TAP is a project of the Center, which investigates the management and sale of government property, including intellectual property rights from government funded R&D. Our mailing address is P.O. Box 19367, Washington, DC 20036. I can be reached by telephone at 202/387-8030 and via the Internet at love@essential.org.

My testimony today will:

- briefly summarize the nature of our research into the government's role in funding pharmaceutical R&D,
- describe the difficultly that we have encountered in obtaining information about the government's role in drug development,
- discuss the findings of the June 1994 Department of Health and Human Services Office of Inspector General, report on under reporting of federal involvement by the Scripps Research Institute,
- discuss the NIH Role in Protecting the Public Interest, and
- offer suggestions for remedial action.

II. Brief Summary of TAP Research into the government's role in funding pharmaceutical R&D.

In June 1991, this subcommittee asked TAP to provide testimony on a Cooperative Research and Development Agreement (CRADA) between Bristol-Myers Squibb (BMS) and the National Cancer Institution (NCI), regarding the development of taxol.[1] Our review of

[1]Our comments are reported in U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, *Exclusive Agreements Between Federal Agencies and Bristol-Myers Squibb Company for Drug Development: is the Public Interest Protected*, Serial No. 102-35, U.S. Government Printing Office, Washington, DC, July 29, 1991.

the NCI BMS taxol CRADA was followed by a much broader review of the government's role in the development of new drugs.

For example, in a study presented in February 1993, TAP examined the federal government's role in the development of all FDA approved cancer drugs that were discovered since 1955, and found that 34 of the 37 cancer drugs were developed with significant federal support.[2]

Earlier this year TAP presented a study of all "priority" drugs approved by the FDA from 1987 to 1991. During this 5 year period the FDA issued 2,270 drug approvals, but most were for generic drugs or new combinations of existing compounds. Only 117 of the new drug approvals involved so called "New Molecular Entities" (NMEs), which is the name given to drugs which are distinctly different in composition from drugs already on the market. Of these 117 NMEs, only 30 were judged by the FDA to be drugs that were used in the treatment of severe illnesses (FDA class E or AA drugs) or to represent a substantial gain in therapeutic value (FDA efficacy rating of A).[3]

Of these 30 "important" new drugs approved by the FDA, 15 benefited from significant funding by the U.S. government. When one considers the country where the drug was first discovered the government's role is even more important. 17 of the "important" new drugs were discovered in the U.S. Of these drugs, 12 were developed with significant government funding - that is, 71 percent were developed with significant government funding.

The U.S. government spends an enormous amount of money on health care research, and this investment has been very productive. On the basis of our research, we have concluded that while the private sector's R&D investments are also large, they tend to be directed at the lower risk ventures, and often are directed at the development of so called "me too" drugs, which do not represent significant improvements in therapy, but rather are marginally different methods of treating illnesses which represent large markets, measured by the companies in the number of dollars they will receive from consumers.

One of the more interesting findings of our research was the fact that the drugs developed with government funds were much more expensive than the drugs developed with

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[2]Ralph Nader and James Love, "Federally Funded Pharmaceutical Inventions," included in U.S. Senate, Special Committee on Aging, *The Federal Government's Investment in New Drug Research and Development: Are We Getting Our Money's Worth*, Serial No. 103-1, U.S. Government Printing Office, Washington, DC, February 24, 1993.

[3]James Love, "Prescription Drug Benefits and the Clinton Health Care Plan," prepared statement, testimony before U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment, February 8, 1994.

only private funding. For the 30 drugs in our study, the median cost of the NMEs which were developed with government funding was $4,854, while those drugs developed without government funding cost $1,626.[4] That is to say, the drugs developed with government funding were about 3 times more expensive than the drugs developed with private funding. Clearly the drug companies were not "passing" on the benefits of government funding to the U.S. consumers, who pay for the research.

We have found that the federal government's role in the development of new drugs is much larger than is generally recognized, particularly for the most important new drugs.

III. Difficulties in obtaining information about the government's role in drug development.

Our own research into the government's role in the development of new drugs has been difficult and time consuming, due to the lack of federal agency information regarding the government's role in the development of new drugs, failures to report government funding of research on patent applications, and a lack of candor by pharmaceutical companies regarding the government's role in the development of new drugs.

As noted in the June 15, 1994, report by the Office of the Inspector General (OIG), which is discussed in more detail below, there is shocking failure to identify federal funding in patent applications. We have found this to be a common problem, not limited to Scripps. Indeed, we never rely upon the information in patent applications when trying to ascertain the government's role in funding new inventions.

Neither NIH, PHS nor HHS compile information on the amount of federal involvement in individual pharmaceutical drugs on a regular basis, except for AIDS drugs, where patient groups and journalists have been particularly interested following the dispute over the pricing of AZT. This is surprising, since one might expect federal agencies to call attention to the successful outputs from their research budgets. In fact, it is nearly impossible to find anyone at most federal agencies who can even speculate what the public has done to support the development of a particular drug.

Every year there are important new drugs entering the market with brand new pricing controversies. Now that the pharmaceutical companies have broken the $100,000 price barrier, we expect these pricing controversies to escalate, particularly in light of the Clinton health care plan's combination of mandatory drug coverage with no price controls. Because we have done a great deal of research on government funded drugs, we are often

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[4]The cost of a drug was based upon a completed treatment or one year of treatment, whichever was less. The data are presented in "Prescription Drug Benefits and the Clinton Health Care Plan," Ibid.

asked if we know what the government has done for new drugs entering the market. That information is usually difficult to track down. The FDA doesn't collect or disseminate information on the government's role in funding the R&D, and the agencies which may have funded the research rarely yield any useful information without very persistent digging by the researcher. Even when it is widely acknowledged that the government funded much of the research, it typically takes a letter from a member of congress just to get an accounting of the total amount of dollars involved.

When we ask research staff from NIH, a university or a company, whether or not federal funds were used in the development of a drug, the most common response is "I don't know." Sometimes we receive piece-meal information about a grant or two that they know about. In other cases, we are given misleading information. For example, when Michael Ward from our office was doing research on Roberts Pharmaceutical's drug Supprelin (histreline acetate), one university researcher who received industry research support told him that the research on the use of histreline acetate for precocious puberty was entirely private. But two days later Mr. Ward was able to talk with Dr. William Krawley of Massachusetts General Hospital, who told him that during about ten years of NIH funded research on gondatropin releasing hormones, the doctor had used histreline acetate in the treatment of precocious puberty, and that this research was the source of the largest group of data used in the NDA. Had Mr. Ward believed the first researcher, who seemed to be in position to know, we would have incorrectly concluded that Supprelin was developed entirely with private funds. This type of gum shoe activity is really quite time consuming, and creates a barrier for public policy researchers who want to learn more about this role of the federal government in drug development.

While we encourage much better reporting on patent applications, this will only solve some of the problems. As the subcommittee knows, many important new drugs are not patented, but may exercise considerable monopoly pricing power. Examples of this include drugs such as Ceredase, which has market exclusivity under the Orphan Drug Act, or Taxol, whereby BMS benefits from a CRADA which gives the company the exclusive rights to use federal research data for purposes of obtaining FDA marketing approval.

There are also a number of cases where the patent application may pre-date crucial government funded research. For example, consider the case of levamisole, a drug used to treat colon cancer. Tetramisole and its close cousin levamisole were discovered to be effective worm remedies for a broad range of nematodal infections in humans, cattle, pigs, sheep, and poultry. Beginning in the 1960's, a series of independent observations led to the conclusion that tetramisole and levamisole "did more than merely kill nematodes." For example, when tetramisole was used to deworm beagles, the pre-weaning mortality rate changed from 1 out of 4 to 1 out of 10. Cattle in Chad treated with tetramisole benefited from an increased resistance to a contagious pneumonia, and levamisole was an apparent

cure for a herpes-like viral infection in monkeys in an Antwerp Zoo.[5]

In 1971 a large scale clinical research program was started to empirically test the effect of levamisole in human diseases possibly caused by impaired cellular immune mechanisms, but the scientific community remained skeptical of the drug's usefulness. In 1986 Janssen Pharmaceutica, a subsidiary of Johnson and Johnson, received a use patent for the idea of using levamisole for "Aiding the Regression of Neoplastic (tumorous) Disease." But the most important clinical work occurred after the J&J patent was obtained. In 1980 the North Central Cancer Treatment Group (NCCTG) issued a report on the benefits from the use of levamisole for the treatment of colorectal cancer, based upon a federally funded research project. In 1990 a more comprehensive study was funded by PHS, which included contributions by the Eastern Cooperative Oncology Group, the Southwestern Oncology Group and the Mayo Clinic. Both of these studies were crucial in the development of levamisole as a treatment for colon cancer. However, neither of these studies could have appeared on the patent, which was issued in 1986.

In general, the government's contribution to the research may occur before or after the patent is obtained, or there may be no patent at all, if the research has entered the public domain.

IV. The June 1994 Inspector General Report on the Scripps Research Institute.

The June 15, 1994, report by the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS), entitled *Under Reporting Federal Involvement in New Technologies Developed at the Scripps Research Institute*[6], provides a shocking illustration of the under reporting of the federal government's role by non-federal recipients of federal funding for pharmaceutical research, and the lack of oversight by the National Institutes of Health.

As a result of this subcommittee's excellent work, we now know that the Scripps Research Institute (SRI) has been engaged in a bewildering array of contracts between SRI research scientists and administrators and private pharmaceutical companies, including side deals that involve stock options and consulting payments for the personal benefit of these individuals. The OIG reported that SRI failed to disclose at least 43 out of 94 patented inventions that benefited from NIH's $70 million per year in grant and contract funding, is a matter of illegal activity that deserves immediate action, including such sanctions as federal taking of patent rights, which is provided for under 35 USC Section 202.

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[5]This account taken from Paul A. J. Janssen, "Levamisole as an adjuvant in cancer treatment," *Journal of Clinical Pharmacology*, 1991; 31: 395, and U.S. Patent No. 4,584,305.

[6]CIN: A-15-93-00029.

As Representative Wyden has pointed out in his June 13, 1994, letter to NIH Director Dr. Harold Varmus, the under reporting of federal involvement in new technology development is closely related to the ability of the federal government to exercise a number of important property rights. As noted by the OIG report, the Bayh-Dole Act[7] gives broad property rights to non-profit and small business recipients of federal research grants, including the rights to receive titles to patents and to license inventions for development on an exclusive basis, without payment of royalties to the government, which funded the research. These rights are not unlimited, however, as the law reserves important rights for the government, in order to achieve public interest objectives, such as requiring local manufacturing, providing the government with a royalty free license to the patent, and providing "march-in" rights which give the government the right to provide compulsory licensing of the invention in order to achieve a number of public interest objectives.

The under reporting of federal involvement should be considered a deliberate act by the grant recipient, since it allows the grant recipient to overstate the degree of risk associated with the development of the technology, and it reduces the likelihood that the government will exercise its rights as a funder of the R&D. The omission of information about the government's role in the development of the invention on a patent application is a particularly serious matter, since the patent applications are prepared by lawyers, who are reasonably presumed to know the law.

According to 35 USC Section 200, it is the policy and objective of Congress to:

> . . . ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions;[8]

The mechanisms to accomplish these public purposes include unambiguous requirements regarding disclosure and Government rights to the patent. Under 35 USC Section 202, each funding agency must provide requirements in contracts that require that:

> . . . the contractor disclose each subject invention to the Federal agency within a reasonable time after it is made and that the Federal Government may receive title to any subject invention not reported to it within such time.[9]

> . . . With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practices for or on behalf of the United States

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[7]Public Law 96-517, as amended by PL 98-620.

[8]35 USC Section 200.

[9]35 USC Section 202(c)(1).

or any subject invention throughout the world,"[10]

. . . An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention."[11]

The government's "march-in" rights, as defined in 35 USC Section 203, are appropriately broad, and highly relevant to pharmaceutical inventions developed with government support. The federal agency has the right to require the contractor or its assignee or licensee to grant non-exclusive, partly exclusive, or exclusive licenses to the patent to a third party or parties, if the agency determines that:

. . . action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention . . .[12]

action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;[13]

or that action is required in order to meet public use requirements or to enforce preferences for U.S. industry.

In our view, under Sections 200, 202 and 203, the government has the authority to systematically review the prices for drugs developed with government grants, and to order compulsory licensing of technologies in order to "alleviate" the "health" needs of the public, when the prices are found to be "unreasonable." Surely there are drug pricing abuses which warrant such action. However, in order for this to occur, it is necessary for the government to be informed that the invention was developed with federal funds, and to systematically organize and manage that information, including routine dissemination of the information to the public.

V. NIH Role in Protecting the Public Interest

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[10]35 USC Section 202(c)(4).

[11]35 USC Section 202(c)(6).

[12]35 USC Section 203(a).

[13]35 USC Section 203(b).

The OIG report raises a number of important issues relative to NIH's potential role in protecting the public interest. According to Dr. Lee's May 24, 1994 memorandum to the OIG, the NIH awards 28,000 research grants and 1,400 contracts to approximately 1,700 entities every year. The OIG report placed fy 1992 NIH grant and contract awards at $6.2 billion, representing a public investment in R&D of about $90 for a four member household.

Not only is NIH woefully understaffed with regarding to the office that receives and manages the disclosure reports, but it does not appear to have any plans, even now, to conduct the types of independent audits and investigations that will increase the rate of truthful reporting.

In this regard, we believe the public interest would be served by a policy of imposing strong sanctions for non-reporting, such as taking patent rights under 35 USC Section 202, in order to send a signal to the grant and contract recipients that such omissions will not be tolerated.

We have good reason to be highly skeptical of NIH as a guardian of the public interest, and it may be necessary to rethink the way that government delegates important public interest oversight responsibilities.

The failure of NIH to routinely collect and disseminate information about the government's role in the development of new drugs does not appear to be an accident. Rather, it is just one more example of NIH's efforts to accommodate the pharmaceutical industry's interest in a wide range of matters. When we began our research into taxol, we were surprised at the hostility of some NCI officials over a number of routine questions we were asking relative to the true extent of the BMS role in the development of taxol, or the government's actual costs of producing taxol. I have testified before this subcommittee on two occasions regarding the NCI/BMS taxol CRADA, and I simply remind this subcommittee of Dr. Bruce Chabner's spirited defense of the BMS pricing of taxol, and his eagerness for NCI to remain as ignorant as possible about any of the facts regarding the investments BMS was required to make during the development of the drug.[14] For example, despite the fact that publicly available SEC documents revealed the fact that BMS was obtaining clinical grade taxol from the Hauser Chemical company, the NCI's former contractor, for less than $.25 per milligram, and reselling the drug to the public for $4.87 per milligram, Dr. Chabner testified that he estimated costs of production for taxol were 25 to 35 percent of its price, which would be $1.22 to $1.70 per milligram. The fact that Dr. Chabner was off by a factor of 5 to 7 times the actual production cost cannot be dismissed as close enough for government work, since NCI itself had used Hauser as a contractor, and NCI officials clearly knew that the unit costs fell with larger production runs.

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[14]Dr. Chabner's comments are included in the published transcripts of the January 25, 1993, subcommittee hearing, *Pricing of Drugs Codeveloped by Federal Laboratories and Private Companies*, Serial No. 103-2.

As the subcommittee is aware, we have been highly critical of the methodologies used by NIH to address the issue of drug pricing in CRADA and license agreements. We have asked on a number of occasions to work constructively with NIH to modify its model CRADA and license agreements in order to obtain better data about the economics of government funded drugs, and also to address a number of concerns that we have about the NIH fair pricing methodology. To our knowledge, we are the only non-industry affiliated group which has expressed such an interest on a regular basis.

Earlier this year Dr. Harold Varmus announced a NIH CRADA Forum, dealing with "perspectives, outlook and policy development." This forum will be held on July 21, 1994 at the Bethesda Holiday Inn, and will include three "point/counterpoint" panels on CRADA issues. My employer, Mr. Ralph Nader, personally asked Dr. Varmus if I could be included on one of the panels, representing the taxpayer and consumer point of view. Mr. Ward from our office was later asked to provide copies of my vita to Barbara McGarey, the Deputy Director of the NIH Office of Technology Transfer, which he did on June 6. About one and half weeks later, Mr. Ward contacted Barbara McGarey, and was informed that Dr. Varmus denied our request to participate in the CRADA forum, and that Dr. Varmus only wanted industry and government panelists. We were told that we could appear during the public comment period, which takes place after the panel discussions, and just before the dinner and panel writing session.

We don't think that Dr. Varmus is required to include me or any particular person for this or any other panel on this topic, but we were dismayed by the lack of balance in the forum. This, however, is typical of the agency. NIH sees itself as a partner with industry, and it has become highly sympathetic of the industry views on issues such as drug pricing and reporting requirements. Why is it that the U.S. government does not collect data on drug prices, does not routinely collect data on drug development costs, even for drugs developed with government funding, and does not express the slightest interest in these matters? There are undoubtedly several answers.

The more benign explanation is that NIH officials believe that the only important public interest concern is the rate of which new drugs are developed, and since, in this view, the costs of drug development to consumers and taxpayers are irrelevant, NIH should avoid raising pricing or reporting issues, since the industry, which remains a key player in drug development, is clearly hostile. There are also less benign reasons. NIH officials often seek employment in the private sector after their government service, or anticipate lucrative consulting arrangements with the private sector if they obtain a university appointment. What's good for the industry may eventually be good for them too. Indeed, as Dr. Robert Wittes has shown in the case of Taxol, one can work on a research project for NIH, then leave the government to help a drug company commercialize the discovery, and then return to the same government agency and begin a new research project.

In our view, the public interest is served by policies that enhance the rate of new drug development, while protecting the consumer and taxpayer interests. There can be no

doubt but that financial reporting requirements and fair pricing rules are negatives, from the point of view of investors. After all, its always better, from the point of view of the pharmaceutical industry, if one can obtain public funds without any accountability what-so-ever. But there is not necessarily a negative trade-off between greater accountability and the rate of innovation in drug development.

The federal government and consumers have finite resources, and if NIH and other federal agencies would do a better job of protecting consumer and taxpayer interests, the same amount of R&D overall could be undertaken with lower consumer drug prices or taxpayer support, or alternatively, a higher R&D effort could be supported by the same amount of consumer and taxpayer spending. When money doesn't grown on trees, the issue is not whether more money gets a bigger bang, but rather, how does one get the biggest bang for the buck? This question can't be answered without better data.

VI. Suggestions for Remedial Action.

Congress should direct HHS, the U.S. Patent and Trademark Office (USPTO), and the FDA to work together to develop a system to monitor and report on the role of federal support for technologies used for health care. This system should include information on patented and non-patented inventions, as well as on federal support which occurs before and after patents are granted. Every FDA NDA should include a report that would be available to the public which describes the role of the federal government in supporting the research that led to the NDA, including such details as contract and grant numbers and the amount of money involved.

HHS should announce to all the non-federal entities that have received public support from NIH and other research agencies that HHS will give a 120 day grace period, and then begin a random audit of reporting requirements, with a public promise to take no less than 30 percent of all patents for which the entity failed to make a proper disclosure, and to impose other penalties, such as a two year moratorium on future grants and a 50 percent cut in overhead allowances for four years.

Congress should also insist that an office independent of NIH routinely audit the NIH compliance with the reporting and public interest sections of the Bayh-Dole Act.

Thank you for the opportunity to appear today to address this important issue. This concludes my prepared testimony.

STATEMENT OF PROFESSOR MICHAEL H. DAVIS*
to the
United States House of Representatives
Committee on Small Business
Subcommittee on Regulation, Business Opportunities, and Technology
July 11, 1994

I have been asked to discuss several features of the Bayh-Dole Act, 35 U.S.C. § 200 et seq., including 1) the apparent under-reporting by the Scripps Institute of inventions produced by Scripps pursuant to federal contracts, 2) the steps NIH should take with Scripps in this particular matter, 3) the role other government agencies should play in overseeing NIH contractors, 4) the problems raised by such under-reporting, including possible examples involving the drug AZT, 5) the possibility that the Scripps problem is part of a larger problem common to the majority of NIH researchers, and 6) whether the rights identified in the IG report as needing better protection are sufficient to protect and serve the public interest in the commercialization of Federally developed technologies.

While all six issues are important and of interest to me, I have chosen to address only the last three, since I am most familiar with the AZT example[1] and my general work in patent law policy has led me to devote a great deal of my professional time

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1. The author served as co-counsel to plaintiffs in People with AIDS Health Group v. Burroughs Wellcome Co., 1992 U.S. Dist. Lexis 578.

to considering the changing role of government and the private sector in technological innovation and how patent law and policy should adjust to that transformation.

1. AZT, Bayh-Dole, and "march-in" rights.[2]

Under-reporting of inventions developed with government support means, among other things, the government cannot track the compliance of contractors who are required not only to commercialize such inventions but also market them at reasonable prices[3] (as well as comply with other goals of Bayh-Dole, such as the requirement that such inventions be commercialized by U.S. firms). To the extent the government can better track these inventions, contractors will be encouraged to comply with Bayh-Dole, because the failure to comply with Bayh-Dole can trigger "march-in" rights by the government, allowing the licensing of such inventions to other firms.

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2. Because I have been asked to address, among other things, the effect of "march-in" rights upon compliance with the Bayh-Dole Act, I use that term throughout to refer to the possible exercise of governmental rights for failure to comply. However, march-in rights are triggered not by the procedural failure to disclose government support but by the failure to comply with various substantive provisions of the Act such as the failure to practically apply the invention, the presence of health or safety problems, the failure to implement meaningful public use, or the failure to procure domestic commercialization. 35 U.S.C. § 203.

On the other hand, the failure to disclose government participation seems to trigger absolute forfeiture of title to the invention, a far more serious, and therefore effective, penalty. 35 U.S.C. § 202(c)(1).

3. "to establish that the invention ... and ... its benefits are ...available to the public on reasonable terms." 35 U.S.C. § 201 (f).

The anti-AIDS drug AZT was invented by government scientists. The patenting of its use[4] against HIV by the Burroughs Wellcome company and the oppressively high price charged for it is a notorious example of how such unpoliced private exploitation of publicly developed inventions can be abused. Partially because Burroughs Wellcome, however, was not a small business subject to Bayh-Dole, the lessons that AZT presents for the Scripps situation are not immediately obvious. But it is a fact that the high prices Burroughs Wellcome initially demanded were eventually lowered because of the threats of Congressional action, combined with determined public opinion and the eventual filing of lawsuits challenging the validity of the Burroughs Wellcome patent.[5]

It was undoubtedly the fear of Congressional action, including the possibility that the federal government would seize the AZT patent under eminent domain theories[6], that forced

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4. Burroughs Wellcome obtained a patent only on the use of AZT against AIDS and HIV infections; it was unable to patent the chemical itself since it had already been discovered a decade earlier by NCI contractors.

5. See Milt Freudenheim, "Maker of Schizophrenia Drug Bows to Pressure to Cut Cost," The New York Times, December 6, 1990, Section A, Page 1. ("Outcry over soaring drug prices has been growing steadily. Last year, the Burroughs Wellcome Company reduced its price for AZT, the AIDS drug, to $6,500 from $8,200, after AIDS advocacy groups staged protests and mobilized support in Congress."); See also, "Aids Drug Patent Challenged in Suit," The New York Times, March 20, 1991, Section A; Page 19"

6. See 28 U.S.C.S. § 1498.

Burroughs Wellcome to lower the price. The seizure of a patent under eminent domain theories is similar, though more draconian, than the "march-in" rights afforded the federal government under Bayh-Dole.[7] But in many ways the economic dynamics are the same; the threat that the government might interfere with the exclusive monopoly rights of the patent holder logically acts as a brake on excessive pricing and other abusive practices allowed by an otherwise unpoliced patent monopoly.

Thus, the AZT case is strong evidence that Scripps and other government contractors subject to Bayh-Dole a) will more readily respond to the public interest when their patent monopolies are subject to government intervention such as "march-in" rights, and b) will logically try to minimize the reporting of inventions that are subject to Bayh-Dole to escape such intervention. The need for close scrutiny and policing of the reporting requirement seems therefore obvious.

While not directly relevant to the present subcommittee inquiry, it is certainly important for future legislative consideration to briefly describe the scandalous nature of the Burroughs Wellcome AZT patent and why Bayh-Dole could not address or remedy the problem. First, Burroughs Wellcome is not a "nonprofit organization or small business firm"[8] otherwise entitled to the disposition of patent rights and subject to

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7. 35 U.S.C.S. § 203.

8. 35 USCS § 202.

march-in procedures. Importantly, however, Burroughs Wellcome's parent corporation is a British charitable organization which might have come within the spirit, if not the letter, of Bayh-Dole. Second, Burroughs Wellcome may not have been a contractor pursuant to a funding agreement, since it profited from NIH testing of its chemicals, but had no clear agreement with NIH and, in any event, Burroughs Wellcome would surely have claimed that its invention was not "conceived or first actually reduced to practice in the performance of work under a funding agreement"[9] Finally, much of the government-subsidized research--including especially the very invention of AZT--that virtually gave Burroughs Wellcome the AZT patent cost-free was accomplished many years earlier, and the truly crucial testing of AZT on the dangerous virus was done at tremendous taxpayer expense but arguably after Burroughs Wellcome would claim it had already made its so-called invention.

All of those problems, however, have less to do with policing the present Bayh-Dole Act than with expanding it some day to the much wider range of government-subsidized technology outside the present Act's scope.

2. The larger problem of private sector compliance and reporting under Bayh-Dole.

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9. 35 U.S.C. § 201(e).

Under Bayh-Dole, a contractor must report by placing the appropriate legend in a patent application that an "invention was made with government support", thus placing any resulting patent within Bayh-Dole. Every year, hundreds of issued patents bear this legend[10]. But the problem suggested by the Scripps outrage is the inverse: how many patents are granted without such designation, thereby escaping the Act, and the possible exercise of Government rights, including march-in rights?

Compliance with Bayh-Dole is essentially self-enforcing and therefore unreliable, because any denial by an inventor of government support with respect to an invention that was even arguably outside the bounds of a government contract would be, by definition, self-serving. As a result, logically, the Inspector General's Report[11] suggested

> "that PHS have NIH develop procedures to obtain, from the USPTO, information on patents issued to NIH grantees...."[12]

The response of PHS was particularly disheartening, stating

> it does not agree ... if the intent of the recommendation requires NIH to validate USPTO data against NIH data for all grantee patents not indicating Government support. The PHS claims that the latter would require too much work.[13]

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10. 35 U.S.C. § 202(c)(6).

11. Memorandum from Inspector General June Gibbs Brown to Philip r. Lee, June 15, 1994.

12. Id. p. 9.

13. Id.

The position of PHS is simply absurd, because it suggests policing only those applications on which the applicant has already admitted that which is supposedly being policed. It is exactly and only those applications which do not have the legend which require further policing, and exactly those upon which the PHS declines to act, because it would involve work.

The opportunities for evading Bayh-Dole, through its self-reporting mechanisms, are difficult to overlook. First of all, the contractor must identify the date upon which the invention was first conceived or reduced to practice.[14] The definitions of both of those concepts are highly fluid, and are continually litigated[15]. With such vague perimeters, it would perhaps require a masochistic contractor to choose the date which burdened him rather than one which did not. Second, a contractor must decide that a particular innovation was made "in the performance of work under a funding agreement."[16] This is similar to deciding whether the work of an agent is that of an employee or that of an independent contractor, for in both situations the "scope of employment"[17], or in this case the scope of a "funding agreement" must be decided. Thus, with so much temptation to choose less

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14. 35 U.S.C. § 201 (e).

15. See Credle v. Bond, 30 U.S.P.Q.2D 1911 (Fed. Cir. 1994)(reduction to practice); Monoplastics, Inc. v. Caldor, Inc., 378 F.2d 20 (2d Cir. 1967)(conception).

16. 35 U.S.C. § 201 (e).

17. See Community for Creative Non-Violence v. Reid, 490 U.S. 730; 109 S. Ct. 2166; 104 L. Ed. 2d 811 (1989).

burdensome--and more potentially profitable--conclusions, it is highly unlikely that, without close oversight, Bayh-Dole will work as intended.

In fact, however, the most simple and unsophisticated search of USPTO records indicates a wealth of patents demanding further investigation. This author, in less than one hour on the evening before this hearing, conducted an electronic search of the patent files on the Lexis legal database. Randomly choosing 1985 as a sample year, a search of patents for that year revealed several hundred patents bearing the legend. Randomly choosing the first five inventors' names, a second search revealed 137 patents issued to those five inventors. But only 30 of those patents bore the legend. One hundred and seven patents were issued to those five inventors without the legend, and of those 107, 55 were issued to those five inventors after each of their first government contracts. Of those 55 patents, 36 were plainly within the area of research for which the first government grant was made. In other words, only 30 patents contained the legend while 36--in the same area of work as the first government grant--contained no such admission.

If that random sample is representative, and there is no reason to think that it is not (although clearly a larger sample needs to be taken for reliable results), inventors benefiting from government support may be identifying less than half of their inventions with the appropriate legend. Or, more

depressingly, Bayh-Dole is being evaded more often than it is being obeyed.

3. Bayh-Dole and protecting the public interest in government-supported technological innovations.

Bayh-Dole's provisions for march-in rights are the wave of the future. It is clear that a patent system premised on a completely private sector producing technological innovations is today out of date. The 17 year patent monopoly which is thought appropriate for private sector investments is, by definition, inappropriate for innovations which are produced through substantial public sector participation, for the private sector does not need and cannot justify the full 17 year term to recoup an investment which has been provided in whole or in part by public funds. Bayh-Dole's attempt to encourage commercialization through preferences given to small and non-profit institutions is thoughtfully balanced by the prophylactic measures, such as march-in rights, designed to police those institutions which fail to comply with Bayh-Dole's policies. Those rights are fully justified by the fact that the patentees are enjoying a 17 year monopoly which is unsupported by a corresponding private investment.

Thus, to the extent that public sector funds produce technological innovations, strict compliance with Bayh-Dole is essential. To rely upon self-policing with regard to valuable properties is plainly preposterous. This is especially true with

regard to intellectual property, the only valuable property which is, by its very nature, intangible and therefore untraceable.

Can it be too much work for the government to carefully, and honestly, police compliance with Bayh-Dole? Although the Act contains no specific punitive measures[18], the consequences for non-compliance seem sufficiently serious--and potentially profitable to the government--to avoid abuse if the Act is responsibly policed. The result of a failure to disclose government participation is loss of title to the invention.[19] The cost of hiring staff to police this appears to be far less than the potential royalties that such forfeited inventions would fetch.

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18. Several measures of the Act are designed to discourage governmental misconduct, and to prevent unwarranted retentions of title to inventions by the government. E.g., 35 U.S.C. §(a),(b)(1). Apparently, when the Act was enacted, contractor abuse and non-compliance was not perceived to be as serious a threat to the Act's objectives as reversing the historic government policy of retaining title to technological innovations. Clearly, the time has come to attend to private misconduct as well.

19. "Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

> "That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time." 35 U.S.C. §202(c)(1).

depressingly, Bayh-Dole is being evaded more often than it is being obeyed.

3. Bayh-Dole and protecting the public interest in government-supported technological innovations.

Bayh-Dole's provisions for march-in rights are the wave of the future. It is clear that a patent system premised on a completely private sector producing technological innovations is today out of date. The 17 year patent monopoly which is thought appropriate for private sector investments is, by definition, inappropriate for innovations which are produced through substantial public sector participation, for the private sector does not need and cannot justify the full 17 year term to recoup an investment which has been provided in whole or in part by public funds. Bayh-Dole's attempt to encourage commercialization through preferences given to small and non-profit institutions is thoughtfully balanced by the prophylactic measures, such as march-in rights, designed to police those institutions which fail to comply with Bayh-Dole's policies. Those rights are fully justified by the fact that the patentees are enjoying a 17 year monopoly which is unsupported by a corresponding private investment.

Thus, to the extent that public sector funds produce technological innovations, strict compliance with Bayh-Dole is essential. To rely upon self-policing with regard to valuable properties is plainly preposterous. This is especially true with

EFFECTS OF THE NONEXCLUSIVE, ROYALTY-FREE LICENSE RESERVED BY THE GOVERNMENT IN SUBJECT INVENTIONS IN WHICH THE GRANTEE /CONTRACTOR RETAINS TITLE

The Bayh-Dole Act, 35 U.S C 200-211, and the implementing regulation promulgated by the Department of Commerce, 37 CFR 401, provide that with respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world

This license does not require the delivery of patented products to the government, rather it means that the government does not have to pay a royalty for the manufacture or use of the specific invention. Thus, if the government had a contract for the manufacture of materials covered by the patent, it would not have to pay a royalty to the contractor which might otherwise be an allowable cost under the contract. The Federal Acquisition Regulation (FAR) has provisions for negotiated contracts which require the reporting of royalties a contractor must pay and that these costs are not allowable where the government has a royalty-free license This does not normally apply to sealed bid contracts since royalty costs are not separable from the amount of the bid. Neither would it apply to procurement directly from the patentee since no royalty would be applicable.

Prices for drugs purchased by the National Institutes of Health (NIH) as well as the Department of Veteran's Affairs and the Department of Defense have been legislated since 1992 by PL 102585, the Veteran's Health Care Act By law, pharmaceutical manufacturers cannot charge more than 76% of the manufacturer's average non-Federal price This is a significantly greater reduction in price compared to the royalty-free price Royalties are estimated to range from 4 to 7% of the market price of the drug. In addition, pharmaceutical manufacturers that are sponsoring NIH clinical drug trials oftentimes provide the drugs free, at cost, or at significantly reduced cost.

August 24, 1994

REPORT ON PATENTS AND LICENSING ACTIVITIES SUPPORTED BY NIH EXTRAMURAL FUNDS: A PILOT STUDY OF 20 ACADEMIC INSTITUTIONS

A pilot study is described herein, the objective of which was to begin to assess compliance with Federal regulations governing inventions and patents that issue from NIH extramural funding agreements.

On July 7, 1994, a letter was sent to 20 academic institutions chosen to participate in the pilot study. In the letter (included as Appendix 1), each institution was requested to provide various documentation for each patent issued on subject inventions conceived or first reduced to practice under an NIH funding agreement. Upon receipt of the information by the Extramural Invention Reporting Office, within the Office of Policy for Research Administration at the NIH, responses were analyzed and are provided in summary fashion in the Table that follows.

Table I: Patent and Licensing Data from Pilot Study

The Table includes information provided by the 20 institutions. In positions within the Table that indicate "(info not given)", the respondent did not provide any relevant details. Moreover, several of the institutions are noted in the Table as having not provided complete information, due primarily to misunderstanding the scope of our request. These data as well as any other relevant updates provided by the respondents will be conveyed upon receipt by the Extramural Invention Reporting Office.

Further explanations of each column in the Table include:

COLUMN HEADING	COMMENTS
Timeframe	Each institution was asked to provide information for at least the most recent 10 year period. As can be seen, numerous respondents provided data well before the requested timeframe.
# of Grants	Numbers reflect instances in which patents arose from more than one grant, occasions in which grants have led to licensed research tools (non-patented), and/or patent pending activities.
# of Patents Issued	Numbers indicate only active patents.

# Acknow.	This column provides the number of issued patents in which NIH support is acknowledged. In many instances where institutions were not fully compliant, they indicated that certificates of correction had been issued, or were in the process of being filed.
# Licensed	Included in this column are the number of issued patents that have been licensed.
# Exclusive	The number of such licenses that are either exclusive or exclusive within a given field are listed in this column.
# Small Business	The number of licensees that qualify as small businesses (less than 500 employees) are provided in this column.
# Domestic Production	While the letter requested an indication of whether the licensee was a domestic manufacturer, most respondents only indicated if the licensee was domestically-owned. Both types of responses are presented in this column. Efforts are ongoing to refine this information.

TABLE I: PATENT AND LICENSING DATA FROM PILOT STUDY

Institution	Timeframe	# of Grants	# of Patents Issued	# Acknow.	# Licensed	# Exclusive	# Small Business	# Domestic Production
Columbia University	1984 - current	80	60	40	19	11	2	4
Cornell University	1974 - current	82	73	59	14	9	15	32
Duke University	1986 - current	96	19	16	8	8	5	8
Fred Hutchinson Cancer Center	1984 - current	40	25	25	13	6	13	21
Johns Hopkins University	1977 - current	62	50	43	37	40	19	38
Massachusetts Institute of Technology	1984 - current	164	94	94	85	111	90	130
Salk Institute	1979 - present	199	133	110	116	19	630	618
Stanford University	1974 - current	202	98	37	6	7	5	(info not given)
Thomas Jefferson University	1978 - current	53	9	9	11	10	11	11
University of California	1975 - current	214	236	236	116	(info not given)	39	99
University of Chicago	1984 - current	46	28	24	20	7	16	19
University of Cincinnati	1984 - current	22	13	6	10	10	2	10
University of Florida*	1987 - current	55	24	23	23	19	20	28
Univ. of Illinois/Urbana-Champaign	1970 - current	33	30	22	4	1	4	4
University of Iowa*	1976 - current	17	12	12	4	3	2	8
University of Minnesota	1969 - current	151	76	76	54	41	50	63
University of Pennsylvania*	1987 - current	24	10	5	3	(info not given)	2	1
University of Washington	1977 - current	36	39	37	22	14	3	21
University of Wisconsin-Madison*	1988 - current	63	63	(info not given)	(info not given)	(info not given)	(info not given)	(info not given)
Yale University	1983 - current	126	51	50	32	26	7	32

* Data provided by this institution are not complete

APPENDIX 1

July 7, 1994

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Dear 3~,

The National Institutes of Health (NIH) continues to be concerned with the timeliness, completeness and accuracy of reports for inventions made with Federal support as part of its responsibility to ensure grantee compliance with regulations under the Bayh-Dole Act (P.L. 96-517) as amended by the Trademark Clarification Act (P.L. 92-620). In particular, Federal regulations require that grantees submit a written disclosure to the NIH within two months after being notified by the inventor of an invention. Grantees must then elect whether they will retain title to the invention within two years after disclosure. Should the grantee elect to retain title, the NIH is required by Bayh-Dole to ensure that the government retains its rights to Federally-supported inventions by securing a non-exclusive, nontransferable, irrevocable, paid-up license from the grantee and verifying that the patent contains a clause stating that the invention was made with NIH support. NIH also has responsibility for ensuring that grantees make an effort to license to firms that will manufacture the invention substantially in the United States (U.S.) before granting an exclusive license to use or sell the invention in the U.S. In the case of nonprofit organizations, reasonable efforts should be made to give licensing preference to small businesses.

In order to assure that our records are complete and to assist us in monitoring compliance with Federal regulations governing extramural research inventions, please forward, as promptly as possible, but before August 1, a list of issued patents on subject inventions, i.e. inventions conceived or first actually reduced to practice under an NIH funding agreement such as a grant, contract or cooperative agreement. We are providing you with our current list of patents made with NIH support at your institution which can be updated if needed. For each patent, please identify the inventor, NIH grant/contract number, title of patent, patent serial number, name of licensee and amount of annual royalties, if licensed. If this information is deemed

confidential, it should be clearly marked "Confidential." Also, please indicate whether or not the patent contains a clause stating that the invention was made with NIH support, and whether or not the patent is licensed to domestic manufacturers and, in particular, small business firms.

We suggest that the information provided to us be presented in a tabular format. As an example, the initial column would report the inventor's name followed by the NIH grant/contract number, patent title, patent serial number, name of licensee, annual royalties, acknowledgement of NIH support of the invention and whether the patent is licensed to domestic manufacturers and small business. Such a display will greatly aid the input of this information into our database.

We look forward to your prompt response to this request. If there are any questions, please contact Sue Ohata at 301/402-0850 or fax 301/480-8443.

Sincerely yours,

Geoffrey E. Grant
Acting Director, Office of
Policy for Research
Administration

Enclosure

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